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Attorney Docket TRNSV-001C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Makower, et al. )  
Serial No.: To Be Determined )  
Filed: Herewith, November 8, 2000 )  
For: Methods and Apparatus for )  
Bypassing Arterial Obstructions and/or )  
Performing Other Transvascular )  
Procedures )

Art Unit: To Be Determined

Examiner: To Be Determined

Transmittal of a Continuation Utility Patent Application

Express Mail mailing label no. EL636155796US

Box Patent Application  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Transmitted herewith for filing is continuation utility patent application for "Methods and Apparatus for Bypassing Arterial Obstructions and/or Performing Other Transvascular Procedures."

[ X ] The applicant(s) hereby request(s) the filing of the continuation patent application under 37 CFR §1.60, corresponding to co-pending application Serial No. 08/730,327.

[ X ] True copies of the following are enclosed:

[ X ] the prior application as filed, including all one hundred twenty-one (121) pages of the specification (including claims 1-92), an abstract of one (1) page, and all twenty-three (23) sheets of formal drawings; and

[ X ] the oath or declaration filed in the parent application, showing the signatures or an indication it was signed; and,

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jc966 U.S. PTO

jc921 U.S. PTO  
09/708923  
11/08/00

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[ X ] Please amend the specification after the granting of a filing date herein by deleting the paragraph under the heading "Related Applications", and substituting therefore: --This patent application is a continuation of application Serial No. 08/730,327 filed on October 11, 1996.--

[X] Kindly enter in this continuational/divisional application the following preliminary amendment, prior to calculation of the required filing fee:

**IN THE CLAIMS:**

**Please cancel claims 60-92, without prejudice.**

[ ] Check No. [Check No.] covering the filing fee in the amount of \$[Check amount] accompanies this application, calculated as follows:

For	(Col. 1) No. Filed	(Col. 2) No. extra	Small entity Rate	Fee	Or	Other than a Small entity Rate	Fee
Basic fee				\$355	Or		\$710
Total claims	59 - 20 =	39	x 9	\$ 0	Or	x 18	\$
Indep claims	3 - 3 =	0	x 40	\$ 0	Or	x 80	\$
Multiple dependent claims presented		N/A	+ 135	\$ 0	Or	+ 270	\$
			Total	\$355	Or	Total	\$

[ X ] An Assignment of the invention to TransVascular, Inc. was previously executed and is recorded in the United States Patent Office at Reel 8775/Frame 0023.

[ ] A Certificate of Ownership under 37 CFR 3.73 (b) and Power of Attorney.

[ X ] Formal drawings are enclosed.

[ X ] The undersigned is the Applicant's attorney of record in the prior application, and all future communications should be addressed to the undersigned.

[ X ] The statement(s) of Small Entity Status filed in the prior application is (are) still proper.


[ X ] An information disclosure statement was filed in relation to the parent case.

A check in payment of the required small entity filing fee and a signed Power of Attorney will be submitted in response to a Notice to File Missing Parts (Filing Date Granted), which should be mailed to applicant's undersigned counsel at the address shown:

Respectfully submitted,

STOUT, UXA, BUYAN & MULLINS, LLP

Date: November 8, 2000



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CERTIFICATE OF MAILING

I hereby certify that this Transmittal letter, the above-identified documents and papers, and a return postcard are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on November 8, 2000 and is addressed to Box Patent Application, Commissioner for Patents, Washington, D.C. 20231.

Dated: November 8, 2000

By:   
Annette Brooks, Assistant

**METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS  
AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES**

**Related Applications**

5        This application claims priority to United States  
Provisional Applications Nos. 60/005,164 filed October  
13, 1995 and 60/010,614 filed February 2, 1996. The  
entire disclosures of Provisional Applications Nos.  
60/005,164 and 60/010,614 are expressly incorporated  
10    herein by reference.

**Field of the Invention**

15        The present invention pertains generally to medical  
methods, devices, and systems, and more particularly to  
methods, devices, and systems for a) revascularization  
and/or b) performing medical procedures at vascular or  
non-vascular intracorporeal locations within a mammalian  
body.

**Background of the Invention**

**A. Background Relating to Revascularization Procedures**

20        In modern medical practice, it is often desirable to  
bypass segments of artery which have become obstructed,  
diseased or injured. The typical surgical procedures  
used for bypassing of obstructed, diseased or injured  
segments of blood vessel require open surgical exposure  
25    of the artery, and the attachment (e.g., suturing) of a  
tubular graft (e.g., homograft, xenograft, allograft,  
prosthetic or bioprosthetic graft) to the affected artery  
such that one end of the graft is connected upstream of  
the obstructed, diseased or injured segment, and the  
30    other end of the graft is connected to the artery  
downstream thereof. In this manner, arterial blood is  
channeled through the bypass graft, thereby restoring  
blood flow distal to the obstructed, diseased or injured  
segment of artery, and preventing tissue ischemia,  
35    infarction, and other sequelae which may result from  
impaired blood flow through the affected artery.

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Although surgical bypass grafting of arteries has been performed at various locations within the body, it is most typical for such arterial bypass procedures to be performed for the treatment of either i) coronary artery disease or ii) peripheral vascular disease affecting the lower extremities.

i. Coronary Artery Disease

Coronary artery disease continues to be one of the leading causes of morbidity and mortality, throughout the world. The typical etiology of coronary artery disease is characterized by the build-up of atherosclerotic plaque within the coronary arteries. Such deposits of atherosclerotic plaque tend to fully or partially block the flow of blood through the affected coronary arteries, and if untreated can result in myocardial ischemia, infarction and death.

For many years, the traditional surgical treatment of coronary artery disease has been coronary artery bypass surgery wherein the patient is generally anesthetized, placed on cardiopulmonary bypass and the patient's heart is temporarily stopped. A thoracotomy (e.g., a median sternotomy) is performed and the obstructed coronary blood vessels are exposed by surgical dissection. One or more segments of the patient's saphenous vein or internal mammary artery is/are harvested for use as bypass graft(s). The harvested segment(s) of vein or artery is/are then anastomosed to the obstructed coronary artery(ies) to form bypass conduit(s) around the arterial obstruction(s). Such traditional coronary artery bypass surgery is expensive, extremely invasive, and is associated with significant operative and preoperative complications.

One alternative to traditional coronary artery bypass surgery is balloon angioplasty. In balloon angioplasty, a flexible guide catheter is percutaneously inserted into a peripheral artery (e.g., the femoral artery) and is transluminally advanced through the

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Another alternative to traditional coronary artery bypass surgery is intraluminal removal (e.g., atherectomy) or ablation (e.g., ultrasound, laser) of the obstructive matter within the coronary artery. These intraluminal removal or ablation procedures are performed by passing a catheter-mounted removal or ablation apparatus through the vasculature to the site of the coronary obstruction. The catheter-mounted removal or ablation apparatus is then utilized to cut, shave, sonicate, pulverize, or vaporize or otherwise ablate the obstructive matter from the lumen of the coronary artery. These procedures must be performed with caution to avoid perforation or damage to the artery wall, as such perforation or damage can result in hemorrhage or excessive scarring and subsequent reocclusion of the artery lumen. Furthermore, these ablative procedures

Another alternative to traditional coronary artery bypass surgery is intraluminal removal (e.g., atherectomy) or ablation (e.g., ultrasound, laser) of the obstructive matter within the coronary artery. These intraluminal removal or ablation procedures are performed by passing a catheter-mounted removal or ablation apparatus through the vasculature to the site of the coronary obstruction. The catheter-mounted removal or ablation apparatus is then utilized to cut, shave, sonicate, pulverize, or vaporize or otherwise ablate the obstructive matter from the lumen of the coronary artery. These procedures must be performed with caution to avoid perforation or damage to the artery wall, as such perforation or damage can result in hemorrhage or excessive scarring and subsequent reocclusion of the artery lumen. Furthermore, these ablative procedures

Other alternatives to traditional coronary artery bypass surgery have included minimally invasive endoscopic procedures which may, ostensibly at least, be performed through small (e.g., 1-3cm) incisions formed in the patient's chest wall, by insertion of a thoracoscope and associated operative instruments through such incisions. One such minimally invasive coronary bypass procedure is described in United States Patent No. 5,452,733 (Sterman et al.). If perfected, these minimally invasive coronary artery bypass procedures may lessen the discomfort and length of recovery time experienced by patients who undergo such minimally invasive procedures vis a vis those who undergo traditional coronary artery bypass surgery. However, endoscopic surgical procedures of this type typically require a great deal of operator skill and training. Furthermore, as with traditional coronary artery bypass surgery, these thoracoscopic procedures are typically performed under general anesthesia, and typically require that one or more chest tubes be left in place during the

5 thoracoscopic coronary artery bypass procedures require  
that the patient be placed on cardiopulmonary bypass, and  
that the patient's heart be temporarily stopped. Others  
of these thoracoscopic procedures purport to be useable  
without placing the patient on cardiopulmonary bypass,  
10 and without stopping the heart. However, those  
thoracoscopic procedures which purport to be useable  
without cardiopulmonary bypass and heart stoppage are  
relatively complex to perform and typically require  
temporary clamping or ligating of the coronary artery  
15 which is to be bypassed. Accordingly, even those  
thoracoscopic procedures which may be useable without  
cardiopulmonary bypass/heart stoppage are prone to unique  
and significant risks and difficulties due to the  
complexities of the procedure and the need for temporary  
20 clamping or closing off the coronary artery(s) being  
bypassed. Thus, many of the drawbacks associated with  
traditional coronary artery bypass surgery, as well as  
additional potential drawbacks, may be associated with  
these minimally invasive thoracoscopic procedures.

Another previously described procedure which does not actually bypass coronary artery obstructions but which nonetheless may be useable to improve blood flow to ischemic regions of the myocardium, is a procedure known as transmyocardial revascularization (TMR). In the TMR procedure a tissue-penetrable probe, such as a laser probe, is utilized to form numerous full-thickness penetrations through the ischemic myocardial wall, and into the chamber of the left ventricle. Oxygenated blood from the left ventricle then flows outwardly through such penetration tracts, so as to perfuse the ischemic myocardium. Examples of such transmyocardial revascularization procedures are described in United



States Patent Nos. 5,554,152 (Aita et al.), 5,380,316 (Aita et al.), and 5,125,926 (Linhares et al.)

One modification of the TMR procedure requires the formation of a valved and/or internally stented transmyocardial passageway (e.g., an interstitial tunnel formed in the muscular wall of the heart) from the left ventricle of the heart to an obstructed coronary artery, downstream of the obstruction. Such modified TMR procedure, is described in United States Patent Nos. 5,287,861 (Wilk), 5,409,019 (Wilk), and 5,429,114 (Wilk).

**ii. Peripheral Vascular Disease**

Peripheral vascular disease commonly results from the build up of atherosclerotic plaque and/or thrombotic matter within peripheral arteries. In many cases, when arteries of the lower extremities have become obstructed by peripheral vascular disease, a phenomenon known as intermittent claudication results. Intermittent claudication is characterized by the occurrence of pain and progressive weakness in the legs during exertion (i.e., walking or running).

The typical surgical approach to the treatment of peripheral vascular disease, especially in patients who exhibit symptoms of intermittent claudication, is to surgically expose the affected artery and to anastomose a tubular bypass graft (e.g., a tube of woven polyester or expanded polytetrafluoroethylene (ePTFE)) to the affected artery such that one end of the graft is attached upstream of the obstruction, and the other end of the graft is attached downstream of the obstruction. In this manner, arterial blood will flow through the tubular bypass graft and around the arterial obstruction, thereby restoring blood flow to the portion of the artery downstream of the obstruction.

One alternative to traditional arterial bypass graft surgery for the treatment of peripheral vascular disease of the lower extremities, is a procedure known as in situ vein bypass. These in situ vein bypass procedures are

typically carried out by forming at least two (2) open incisions in the leg, to expose the affected artery at sites upstream and downstream of the obstruction. A peripheral vein, which extends through the leg generally parallel to the affected artery, is then prepared by inserting an instrument into the vein to lyse or disrupt the venous valves located within the vein. Thereafter, any side branches which extend from the vein are cut, ligated or blocked by embolization. The prepared vein is then transected at locations above and below the arterial obstruction, and the transected ends of the vein are placed in contact with, and sutured directly to, the artery at sites upstream and downstream of the obstruction. In this manner, arterial blood flow becomes channeled through the prepared segment of vein, such that the prepared segment of vein will act as bypass conduit around the arterial obstruction. Examples of current in situ vein bypass procedures are described in White, R.A. and Fogarty, T.J., Peripheral Endovascular Interventions, Pgs., 166-169, Mosby & Co. (1996).

iii. Trauma and Other Diseases Which May Impair Flow Through Arteries

Various arteries of the body may become damaged by trauma (e.g., lacerations, crushing injury, blunt abdominal trauma) or may become invaded or compressed by extra-vascular disease processes (e.g., to proliferation and ingrowth of an adjacent tumor). The typical surgical approach to treatment of arteries affected by such trauma or disease is to surgically expose and direct the affected segment of artery, and to thereafter a) resect and reconnect or b) bypass the affected segment of artery, to restore arterial blood flow through or around the affected segment of the artery. In many such cases, the segment of artery affected by the injury or disease may be so large as to preclude simple resection, removal of the affected segment, and end-to-end anastomosis of the adjacent cut ends of the artery. Accordingly, in

such instances where resection and end-to-end anastomosis is not an available option, it may be desirable to attach a tubular bypass graft (e.g., a tubular graft formed of woven polyester, or ePTFE) to the affected artery, to bypass the affected segment of the artery.

Although a number of the above-described surgical procedures represent relatively recent advancements whereby the invasiveness and risk associated with traditional surgical approaches have been mitigated, there remains a need in the art for the development of new, safe, and reliable minimally invasive and/or transluminal procedures for bypassing segments of arteries which have become obstructed, injured or affected by disease.

**B. Background Relating to Other Extravascular Surgical/Interventional Procedures**

Many types of surgical and interventional procedures have previously been formed in organs, tissues or body cavities of the body. Traditionally, access to such organs, tissues or body cavities is attained through the formation of one or more open surgical incisions in the body, whereby the affected organs, tissues or body cavities are surgically exposed.

In recent years, substantial efforts have been undertaken to develop "minimally invasive" surgical techniques whereby one or more endoscopes are utilized to view the affected organ, tissue or body cavity, operative instruments or other devices are inserted into the body to accomplish the desired surgical or interventional procedure through relatively small, "minimal access" (e.g., less than 3cm) incisions.

Although the advent of these endoscopic "minimal access" surgical procedures may have advantageous over traditional open surgical techniques insofar as they may minimize the size of the surgical incision, and accordingly, may lead to less post-operative discomfort, such endoscopic procedures are often limited to

procedures within accessible body lumens or cavities which may be filled with clear liquid or insufflated with a gas to provide an open area within which to place the operative endoscope(s) and instrument(s).

5 In view of the limitations associated with the even the most modern "minimal access" surgical and interventional procedures, there remains a need in the art for the development of new methods and apparatus for accessing tumors, organs, tissues and other extravascular  
10 locations within the body, to permit the performance of surgical and/or interventional procedures without the need for forming any open surgical incisions in the body.

#### Summary of the Invention

15 In general, the present invention provides methods for using the vascular system of a mammalian body as a conduit for performing various types of medical procedures. Due to the wide distribution of vessel conduits throughout the body, the vascular system provides a highway through which devices can be navigated  
20 to reach selected treatment sites which may be otherwise only accessible through a direct incision. The specific methods of the present invention include a) revascularization methods, and b) methods for performing various types of medical procedures at extravascular  
25 locations within the body.

The revascularization methods of the present invention generally comprise the formation of one or more extravascular passageways between blood vessels, different locations on the same blood vessel, or a blood  
30 vessel and another blood-containing anatomical structure (e.g., chamber of the heart), such that blood will flow through such passageway(s). In many applications of the invention, it will be desirable for oxygenated blood (i.e., blood which has a  $pO_2$  greater than 50) to be  
35 carried through the extravascular passageway(s) for the purpose of providing or enhancing perfusion of tissues. The extravascular passageways formed in accordance with

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penetrating element (e.g., member, apparatus, flow of energy) from the blood vessel to the selected target location. Also, optionally, the tissue-penetrating element of the catheter device may incorporate a guide  
5 wire lumen or other means for passing a guide wire through the extravascular passageway formed by the tissue-penetrating element.

Further in accordance with the invention, the passageway-forming catheter device of the foregoing  
10 character may be combined with one or more apparatus for orienting the tissue-penetrating element to insure that the extravascular passageway is formed at its intended location. Such orienting apparatus may be mounted upon or incorporated into the passageway-forming catheter, or  
15 may be formed separately of the passageway-creating catheter and used in conjunction with the catheter, from any suitable intracorporeal and/or extracorporeal location. The orienting apparatus may comprise various types of active and/or passive apparatus including, but  
20 not limited to, extracorporeal or intracorporeal ultrasound apparatus, extracorporeal or intracorporeal Doppler apparatus, intracorporeal or extracorporeal radiographic apparatus, magnetic resonance imaging apparatus, tomography apparatus, induction coils,  
25 electromagnetic devices, and various catheter-borne markers which are identifiable by radiographic, sonic, ultrasonic, photographic, MRI, or other means.

Still further in accordance with the invention, there are provided passageway-modifying devices for  
30 debulking, lining, stenting, longitudinally compressing and/or otherwise modifying the extravascular passageway(s) which are formed by the present invention.

Further objects and advantages of the present invention will become apparent to those skilled in the  
35 art upon reading the detailed description of preferred embodiments set forth herebelow, wherein certain

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presently-preferred embodiments and examples of the invention are set forth in detail.

**Brief Description of the Drawings**

Figure 1a is a front perspective view of a human heart showing the typical locations of coronary arteries and veins thereon.

Figure 1b is a rear perspective view of the human heart showing the typical positions of arteries and veins thereon.

Figure 1c is a longitudinal sectional view through an adjacent coronary artery and coronary vein within segment 1c of Figure 1a, wherein blood flow passageways have been formed in accordance with the present invention to bypass an obstruction located within the coronary artery.

Figure 1d is a cross sectional view through line 1d-1d of Figure 1c.

Figure 1e is a diagram of the Triangle of Brouck-Moscheau, an anatomical landmark which is defined by certain coronary arteries and coronary veins of the human heart, as visualized on an x-ray taken from the right anterior oblique view.

Figure 1f is a perspective view of an alternative revascularization method of the present invention wherein an extravascular interstitial passageway is formed from a first location on a blood vessel (upstream of an obstruction) to a second location on the same blood vessel (downstream of the obstruction).

Figure 1f' is a perspective view of the blood vessel shown in Figure 1f, following complete application of the revascularization method of the present invention to form a bypass passageway around the obstruction.

Figure 2 is a perspective view of a human body incorporating a schematic illustration of a transvascular method for performing a medical procedure at an extravascular location within the body, in accordance with the present invention.



Figure 2a is an enlarged perspective view of the target tissue of Figure 2, showing the manner in which a tissue-penetrating element is passed from the passageway-forming catheter into the target tissue.

Figure 2a' is an enlarged view of the target tissue of Figure 2 showing an access conduit which has been advanced through and/or exchanged into the extravascular passageway into the target tissue.

Figure 2b is a schematic showing of an indwelling  
10 delivery/sampling cannula having a subcutaneous injection  
port for repetitive infusion/withdrawal of matter  
into/from or monitoring of conditions in the target area.

Figure 2c is a schematic showing of a catheter inserted through the extravascular passageway for temporarily deployment of a device into, monitoring of conditions in, or infusion/withdrawal of matter into/from the target area.

Figure 2d is a schematic showing of a permanently placed device (e.g., fluid drainage shunt) utilizing the extravascular passageway of the present invention.

Figure 2e is a schematic showing of a catheter inserted through the extravascular passageway of the present invention and into the lumen of another tubular anatomical passageway, for sampling, access, monitoring, or performance of a surgical or interventional procedure within the tubular anatomical passageway.

Figure 2f is a schematic showing of a transvascular procedure for performing extravascular microsurgery, in accordance with the present invention.

30           Figure 3a is a longitudinal sectional view showing  
an unmodified blood flow passageway formed in accordance  
with the present invention.

Figure 3b is a longitudinal sectional view showing an internally lined blood flow passageway formed in accordance with the present invention.

Figure 3c is a longitudinal sectional view showing a longitudinally compressed blood flow passageway formed in accordance with the present invention.

Figure 3d is a longitudinal sectional view showing  
5 a blood flow passageway of the present invention having  
a non-protrusive stent or stented graft positioned  
therewithin.

Figure 3d' is a perspective view showing an optional flange and/or optional projections which may be incorporated into a non-protrusive stent or stented graft positionable within a blood flow passageway of the present invention in accordance with Figure 2d.

Figure 3e is a sectional view through a blood flow passageway of the present invention, having a first  
15 embodiment of a hemiprotrusive or protrusive stent or stented graft positioned therewithin.

Figure 3f is a sectional view through first and second blood flow passageways of the present invention, having a second embodiment of a protrusive stent or stented graft positioned therewithin.

Figure 4a is a schematic illustration of a first approach for forming arteriovenous blood flow passageways in accordance with the present invention.

Figure 4b is a schematic illustration of a second  
25 approach for forming arteriovenous blood flow passageways  
in accordance with the present invention.

Figure 4c is a schematic illustration of a third approach for forming arteriovenous blood flow passageways in accordance with the present invention.

30           Figure 4d is a schematic illustration of a fourth approach for forming arteriovenous blood flow passageways in accordance with the present invention.

Figure 4e is a schematic illustration of a fifth approach for forming an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5a is a longitudinal sectional view of two (2) adjacent blood vessels, illustrating a first means

Figure 5b is a longitudinal sectional view of an adjacent artery and vein, illustrating a second means for orienting, aiming and guiding a tissue-penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5d is a longitudinal sectional view of an adjacent artery and vein, illustrating a fourth means for orienting, aiming and guiding a tissue-penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5e' shows a first type of radiographic  
25 markers which may be utilized in accordance with Figure  
5e.

Figure 5e''' shows a third type of radiographic markers which may be utilized in accordance with Figure 5e. Figure 5f is a schematic showing of a method for utilizing an ultrasonically visible marker to aim, align and/or guide a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5f' is a perspective view of the ultrasonically visible marker shown in figure 5f.

Figure 5g is a schematic view of a method for using MRI to orient, aim or guide a tissue-penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5g' is a perspective view of a first embodiment of a marker visible by magnetic resonance imaging (MRI) to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5g'' is a perspective view of a second embodiment of a marker visible by magnetic resonance imaging (MRI) to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5h is a schematic showing of means for utilizing a doppler apparatus to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5i is a schematic showing of means for a pressure sensing apparatus to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5j is a schematic showing of means for utilizing transmitter and receiver apparatus for orienting, aiming and/or guiding a tissue penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5k is a schematic showing of means for utilizing transmitting and induction coil apparatus for orienting, aiming and/or guiding a tissue penetrating

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exiting of the tissue-penetrating element from the catheter.

Figure 6h is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a eighth means for exiting  
5 of the tissue-penetrating element from the catheter.

Figure 6i is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a ninth means for exiting  
10 of the tissue-penetrating element from the catheter.

Figure 7a is a longitudinal sectional view of a distal portion of the first embodiment of a tissue-penetrating element in accordance with the present invention.

15           Figure 7a' is a cross sectional view through line  
7a'-7a' of Figure 7a.

Figure 7b is a longitudinal sectional view of a distal portion of the second embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7c is a longitudinal sectional view of a distal portion of the third embodiment of a tissue-penetrating element in accordance with the present invention.

25           Figure 7d is a longitudinal sectional view of a distal portion of the fourth embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7d' is a cross sectional view through line  
30 7d'-7d' of Figure 7d.

Figure 7e is a longitudinal sectional view of a distal portion of the fifth embodiment of a tissue-penetrating element in accordance with the present invention.

35        Figure 7e' is a cross sectional view through line  
7e'-7e' of Figure 7e.

5           Figure 7f is a longitudinal sectional view of a distal portion of the sixth embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7g is a longitudinal sectional view of a distal portion of the seventh embodiment of a tissue-penetrating element in accordance with the present invention.

20           Figure 7i is a longitudinal sectional view of a distal portion of the ninth embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7k is a longitudinal sectional view of a distal portion of the eleventh embodiment of a tissue-  
penetrating element in accordance with the present  
invention.

Figure 7m is a longitudinal sectional view of a distal portion of the thirteenth embodiment of a tissue-

Figure 8a is a longitudinal sectional view of a first embodiment of an apparatus for modifying an interstitial passageway formed in accordance with the present invention.

Figure 8c is a longitudinal sectional view of a third embodiment of an apparatus for modifying an interstitial passageway formed in accordance with the present invention.

Figure 8e is a longitudinal sectional view of a  
20 fifth embodiment of an apparatus for modifying an  
interstitial passageway formed in accordance with the  
present invention.

Figure 8g is a longitudinal sectional view of a seventh embodiment of an apparatus for modifying an interstitial passageway formed in accordance with the present invention.

35        Figure 8h' is an elevational view of the device of  
Figure 8h being used to modify and arteriovenous blood



Figure 8i is a longitudinal sectional view of a ninth embodiment of an apparatus for modifying an interstitial passageway formed in accordance with the present invention.

Figure 9a is an elevational view of a first embodiment of a device usable to longitudinally compress an arteriovenous passageway formed in accordance with the present invention.

Figure 9b is an elevational view of a second embodiment of a device usable to longitudinally compress an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9b'' is a perspective view of the device of  
25 Figure 9b partially ejected from its delivery catheter.

Figure 9c is an elevational view of a third embodiment of a device usable to longitudinally compress  
30 an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9e is an elevational view of a fifth embodiment of a device usable to longitudinally compress

Figure 9f is an elevational view of a sixth embodiment of a device usable to longitudinally compress an arteriovenous blood flow passageway in accordance with the present invention.

10           Figure 9f'' is a perspective view of the device of  
Figure 9f as it is mounted within its delivery catheter.

15           Figure 9f'''' is a cross sectional view of the  
device of Figure 9f fully deployed out of its delivery  
catheter.

Figure 10b is a longitudinal sectional view through line 10b-10b of Figure 10.

25           Figure 10d is a cross sectional view through line  
10d-10d of Figure 10a.

Figure 10c' is a schematic view of an optional guide wire/sheath urging apparatus which may be incorporated into any embodiment of the transvascular tissue-penetrating catheter of the present invention.

Figure 10c''' is a schematic showing of the device  
35 of Figure 10c after the tissue-penetrating element has  
penetrated through tissue and into a vascular lumen or  
open cavity.

Figure 11a is a longitudinal section view through the handpiece component of a second embodiment of a transvascular tissue-penetrating catheter device of the present invention.

5        Figure 11b is a partial longitudinal sectional view through a distal portion of the second embodiment of the transvascular tissue-penetrating catheter device of the present invention.

10        Figure 11c is a longitudinal section showing of the device of Figure 11b during a first stage of a tissue-penetrating procedure.

Figure 11c is a longitudinal section showing of the device of Figure 11b during a second stage of a tissue-penetrating procedure.

15        Figure 11d is an enlarged longitudinal sectional view of segment 11d of Figure 11c.

#### **Detailed Description of the Preferred Embodiments**

20        The following detailed description and the drawings to which it refers are provided for the purpose of describing certain presently preferred embodiments of the present invention only, and are not intended to limit the scope of the invention in any way. Indeed, it is to be appreciated that the detailed descriptions and examples set forth herebelow are provided as mere examples or  
25        illustrations of certain ways in which the invention may be utilized or practiced. These examples and illustrations are not intended to provide an exhaustive description of all possible embodiments and examples of the invention but, rather, are illustrative of some but  
30        not all applications to which the invention may be applied.

#### **A. The Methods of the Present Invention**

##### **i. Revascularization Methods**

35        Broadly stated, the revascularization method of the present invention provides a method for establishing one or more passageway(s) 10 through which blood may flow from or into at least one blood vessel. In most cases,

the blood which flows through the passageway will preferably have a  $pO_2$  in excess of about 50.

In some instances the extravascular passageway(s) 10 will be used for bypassing an obstructed, injured or disease-affected segment of an artery. In some 5 embodiments of the invention, only a primary blood flow passageway (e.g., a passageway from the artery upstream of the obstruction) will be formed between an obstructed injured or disease-affected artery (or another unimpaired 10 artery or a blood-filled anatomical structure such as a chamber of the heart), and a vein thereby permitting arterial blood will then be permitted to flow in the retrograde direction through the vein, so as to retroprofuse tissues through the venous vasculature. In 15 other embodiments of the invention, one or more secondary blood flow passageways will also be formed between the obstructed artery and the vein, downstream of the obstruction, such that arterial blood which has entered the lumen of the vein through the primary blood flow 20 passageway(s) may subsequently enter or re-enter the lumen of the artery, downstream of the obstruction, thereby perfusing tissues through the remaining (e.g., unobstructed) portion of the obstructed artery.

Although the anatomical showings provided in Figures 25 1a and 1b are specific to the coronary vasculature, it is to be appreciated that the methods of the present invention may be applied to blood vessels throughout the body and are not necessarily limited the treatment of obstructed coronary arteries (e.g., the femoral-popliteal 30 region, aorta-iliac region, etc.).

With reference to the drawings, Figures 1a and 1b provide detailed showings of the normal vascular anatomy of a human heart wherein coronary arteries are substantially parallel and adjacent to coronary veins. 35 The specific anatomical structures shown in Figures 1a, 1b and 1e are labeled in accordance with the following legend:

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	A.	. . . . .	Aorta
	AIV	. . . . .	Anterior Interventricular Vein
	CA	. . . . .	Coronary Artery
	CV	. . . . .	Coronary Vein
5	CS	. . . . .	Coronary Sinus
	CIR	. . . . .	Circumflex Artery
	IVC	. . . . .	Inferior Vena Cava
	LAD	. . . . .	Left Anterior Descending Artery
	SVC	. . . . .	Superior Vena Cava
10	PA	. . . . .	Pulmonary Artery
	PV	. . . . .	Pulmonary Vein
	TA	. . . . .	Tunica Adventitia
	TM	. . . . .	Tunica Media
	TI	. . . . .	Tunica Intima
15	GCV	. . . . .	Great Cardiac Vein

Figures 1c-1d illustrate a specific application of the present invention, wherein an obstruction OB is located within a coronary artery located on the left anterior aspect of the heart. As shown, the obstructed coronary artery CA is located adjacent, and generally parallel to, a coronary vein CV. A first blood flow passageway 10a is formed between the coronary artery CA and the adjacent coronary vein CV, at a location upstream of the arterial obstruction OB. Also, in the showing of Figure 1c, an optional second blood flow passageway 10b has been formed between the lumen of the coronary vein CV and the lumen of the coronary artery CA, at a location downstream of the obstruction OB. Also, in these figures, optional embolization members 12a, 12b are shown to have been placed within the lumen of the coronary vein CV at sites proximal of the first blood flow passageway 10a, and distal of the optional second blood flow passageway 10b. These optional embolization member serve to guide the flow of arterial blood which enters the coronary artery CA through the first blood flow passageway 10a, through a segment of the adjacent coronary vein CV, and through the second blood flow

passageway 10b such that the arterial blood reenters the lumen of the coronary artery CA, downstream of the obstruction OB. Optional embolization members 12a, 12b may be any one or combination of devices sufficient to  
5 block or impede flow such as coils; hemostatic materials such as collagen, Gelfoam<sup>TM</sup> or fibrin, covered stents or frames, detachable balloons, valve structures clips, fasteners or plugs, etc. Further, the function served by these members may also be accomplished utilizing various  
10 methods including ligation, welding, coagulation, or other surgical methods.

As illustrated in the cross sectional showing of Figure 1d, each blood flow passageway 10 of the present invention is essentially an interstitial tunnel which  
15 extends through the wall of an artery (such as a coronary artery CA) through the wall of an adjacent vein (such as a coronary vein CV) and through any connective or membranous tissue which may be located between the coronary artery CA and coronary vein CV. In this manner,  
20 each blood flow passageway 10 acts as a flow conduit between the lumens of the coronary artery CA and coronary vein CV.

Figure 1e is a diagram of a portion of the coronary vasculature known as the Triangle of Brouck-Moscheau.  
25 The Triangle of Brouck-Moscheau is defined by the left anterior descending coronary artery LAD, the circumflex coronary artery CIR, the anterior interventricular vein AIV and the great cardiac vein, GCV, as shown. Obstructions resulting from the build-up of  
30 atherosclerotic plaque are often found in the proximal portions of the left anterior descending artery LAD and/or the circumflex artery CIR. The revascularization methods of the present invention may be utilized to treat such obstructions of the left anterior descending artery  
35 LAD and/or circumflex artery CIR by forming appropriate blood flow passageways 10 between the arteries and veins surrounding the Triangle of Bouck-Moscheau. For example,

if an obstruction is present in the proximal portion of the left anterior descending artery LAD, a first blood flow passageway 10a may be formed between the great cardiac vein GCV and the circumflex artery CIR and a second blood flow passageway 10b may be formed between the left anterior descending artery LAD and the anterior intraventricular artery AIV, at a location downstream of the obstruction. A lumen blocking member 12 may be placed within the great cardiac vein GCV, proximal to the first blood flow passageway 10a and/or within the anterior interventricular vein AIV distal to the second blood flow passageway 10b such that arterial blood from the circumflex artery CIR will flow through the first blood flow passageway 10a, through the great cardiac vein GCV, through the anterior interventricular vein AIV and into the left anterior descending artery LAD, downstream of the obstruction. Alternatively, in cases where the obstruction is present in the circumflex artery CIR, the first blood flow passageway 10a and second blood flow passageway 10b may be inverted, such that blood flowing through the left anterior descending artery LAD will flow through the anterior interventricular vein AIV, through the great cardiac vein GCV and into the circumflex artery CIR, downstream of the obstruction. In accordance with these examples, it will be appreciated that the revascularization method of the present invention may be utilized in a manner which obtains arterial blood from an artery or from any other source (e.g., left ventricle), and passes such arterial blood into another artery. Moreover, in accordance with the revascularization methods of the present invention, it will be appreciated that the second blood flow passageway 10b may, in at least some cases, be eliminated and arterial blood may be provided to the blood-deprived regions of the myocardium by retroprofusion through the anterior interventricular vein AIV or great cardiac vein GCV.

It will be appreciated that in some applications of the revascularization method of the present invention, the extravascular passageway 10 may comprise an interstitial tunnel which extends from a first location to a second location, on the same blood vessel. As shown in Figure 1f, a blood vessel BV having an obstruction OB formed therein may be bypassed by utilizing a passageway-forming catheter 100 of the present invention whereby a tissue-penetrating element 102 is passed through the wall of the blood vessel upstream of the obstruction, through the adjacent tissue, and subsequently through the wall of the blood vessel downstream of the obstruction. In this manner, an interstitial passageway 10, shown in Figure 1f', forms a bypass conduit around the obstruction OB in the blood vessel BV.

ii. Methods for Performing Surgical or Interventional Procedures at Extravascular Locations

In addition to the above-described revascularization methods, the present invention also includes methods for performing various surgical or interventional procedures at extravascular locations within the body. These methods of the present invention are accomplished by forming one or more extravascular passageways from a blood vessel to an extravascular location (e.g., organ, tissue, body cavity, etc.) and subsequently passing one or more procedure-performing apparatus through the extravascular passageway to accomplish the desired surgical or interventional procedure at the extravascular location. The types of surgical or interventional procedures which may be performed in accordance with this method of the present invention include:

DELIVERY OF THERAPEUTIC MATTER

- Delivery of flowable drug substance;
- Implantation of an implantable drug delivery apparatus (e.g., microspheres, etc.);
- Delivery of medical treatment fluids;



- Implantation of access catheter for ongoing drug dosing;
- Implantation of genetic material, cells, microbial or viral vectors, etc.

5      **TEMPORARY OR PERMANENT DEPLOYMENT OF DEVICE(S)**

- Implantation of stimulator (electrical or physical);
- Implantation of sensor;
- Implantation of electrode;
- 10      • Implantation of transmitter, receiver or transponder;
- Implantation of support member (e.g., stent);
- Implantation of marker (e.g., radiographically visible markers, or solutions.

15      **TISSUE RESECTION, EXCISION OR ABLATION**

- Tissue ablation or destruction;
- Cutting or transection of tissue (e.g., nerve, fibers);
- Resection and removal of neoplasms, diseased
- 20      tissue, etc.;
- Dilation, stretching or other modification of endogenous tissue to restore patency, flow, configuration, or function.

**SAMPLING APPLICATIONS**

- 25      • Sampling of tissue (e.g., biopsy);
- Sampling of solid matter (e.g., calculus, tophi, etc.);

**MONITORING APPLICATIONS**

- 30      • Determining pressure, pH, temperature, oxygen saturation, partial pressure of dissolved gas, ECG, EEG, evoked potentials, or other variables which are measurable at the target area.

Figures 2-2f are provided for the purpose of further describing and illustrating some of the specific  
35      interventional and/or surgical procedures which may be performed in accordance with this embodiment of the present invention. Figure 2 shows a schematic

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illustration of the human body wherein a passageway-forming catheter apparatus 100 of the present invention has been percutaneously inserted into a blood vessel (e.g., femoral vein) and has been advanced through the vena cava, internal jugular vein and great cerebral vein, to a desired location adjacent the extravascular target area (e.g., ventricle of the brain). Thereafter, a tissue-penetrating element 102 is passed from the catheter 100 through the wall of cerebral blood vessel wherein the distal portion of the catheter 100 is located and the tissue penetrating element is advanced through the adjacent brain tissue to an extravascular target location T within the brain. In this manner, an extravascular passageway 10 has been formed from the cerebral blood vessel to the extravascular target location T. As necessary, the passageway 10 which is initially formed by the tissue-penetrating element 102 may be debulked, enlarged or modified in accordance with the apparatus and methods for passageway modification shown in Figures 8a-8h and described in detail herebelow.

Figure 2a is an enlarged view of the target area T and the adjacent blood vessel BV into which the passageway-forming catheter device 100 has been advanced. Initially, the tissue-penetrating element 102 of the passageway-forming catheter device 100 is advanced out of the catheter 100, through the wall of the blood vessel BV, and through tissue which is located between the blood vessel BV and the target area T. The tissue-penetrating element 102 utilized in this application preferably incorporates a lumen 114 through which a secondary guide wire  $GW_2$  may be advanced into the target area T. Thereafter, the tissue-penetrating element 102 may be retracted and removed along with the passageway-forming catheter 100, leaving the secondary guide wire  $GW_2$  in place.

As shown in Figure 2a, an access canula 103 may then be advanced over the pre-positioned secondary guide wire

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GW<sub>2</sub> such that the cannula 103 extends through the vasculature, through the extravascular passageway 10 formed by the tissue-penetrating element 102 and into the target area T. This access cannula may then be utilized  
5 as a conduit for introduction of drugs, implantation of devices, sampling, monitoring, deployment of surgical apparatus or other applications in accordance with the methods for performing surgical or interventional procedures at extravascular locations, described  
10 hereabove.

Figures 2b-2f illustrate specific examples of the types of extravascular surgical or interventional procedures which may be performed in accordance with this aspect of the invention.

15 With reference to Figure 2b, a subcutaneous port apparatus 105 may be mounted on the proximal end of the access cannula 103, and may be utilized for the injection or withdrawal of flowable substances (e.g., drugs, medical treatment fluids, radiographic contrast  
20 solutions, cells, genetic material, microbial or viral vectors, etc.) through the access cannula 103, and into the target area T. Also, the port apparatus 105 and cannula 103 may be utilized to accomplish periodic monitoring of pressure or other conditions at the target  
25 area T (e.g., by filling the cannula 103 with fluid and inserting a needle connected to a pressure transducer into the port apparatus 105, a reading of pressure at the target area T may be obtained). Thus, Figure 2b illustrates the manner in which an indwelling access  
30 cannula 103 having a subcutaneously positioned injection port 105 may be utilized for continuing infusion or withdrawal of flowable matter into/from the target area T. Specific examples of the types of conditions which may be treated by repeated infusions of drugs to a  
35 specific target area T within the body include Parkinsons disease, epilepsy, hypertension, tumors, depression, Alzheimer's disease, sleep disorders, behavior disorders,

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continually drain fluid from the target area T. In this manner, the proximal portion of the access cannula 103 is provided with a plurality of outlet apertures 109 such that excess fluid which collects within the target area T will drain proximally through the lumen of the access cannula 103 and out of outlet apertures 109. The proximal portion of the access cannula 103 having the outlet apertures 109 formed therein may be exteriorized such that excess fluid is drained into an extracorporeally located container or vessel, or alternatively be implanted at another location within the body (e.g., the peritoneal cavity) such that excess fluid will pass into such other area of the body where it can be assimilated by natural physiologic functions without causing damage or harm to the body. One example of such application is the use of the cannula 103 as an indwelling shunt or draining excess cerebrospinal fluid from a ventricle of the brain to a secondary location (e.g., peritoneum) within the body. Because the cannula 103 has been implanted through the vasculature and through the extravascular passageway 10 created in accordance with the invention, the technique used for implantation of the cannula 103 may be performed percutaneously without requiring large surgical incisions as may be typical of other methods utilized to implant fluid-drainage shunt devices used for the treatment of hydrocephalus and other disorders.

Figure 2e shows another specific application of the present invention, wherein the access cannula 103 extends from the blood vessel BV, through the extravascular passageway 10 of the present invention and into the lumen 111 of a secondary tubular anatomical passageway or duct which is the target T in this application. The types of tubular passageways or ducts which may form the target T in this application of the invention include blood vessels, geneto-urinary ducts, exocrine ducts, endocrine ducts and lymph ducts. After the access cannula 103 has

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Figure 2f illustrates yet another specific example of an application of the invention wherein the access cannula 103 extends through the vasculature, through an extravascular passageway 10 of the present invention, and into a target area T such that one or more surgical instruments 113 may be passed into the target area T for the purpose of performing a surgical (e.g., microsurgical) procedure within the target area T. In this manner, an exteriorized control system 115 may be connected to the surgical instrument(s) 113 and may be utilized to effect the desired operation and manipulation of the surgical instrument 113 within the target area T.

Figures 3a-3f, and the detailed description set forth herebelow, describe certain types of extravascular passageways 10 which may be formed in accordance with the present invention. The showings of Figures 3a-3f and the following detailed description are presented as mere examples of types of passageways which may be formed, and are not intended to exhaustively describe all possible types of passageways 10 which may be utilized in accordance with the present invention. Furthermore, it is to be noted that although the showings of Figures 3a-3f are directed to passageways 10 formed between a vein and artery, the various passageway modifications illustrated in Figures 3a-3f are broadly applicable to any or all types of extravascular passageways 10 formed in accordance with the present invention, for which such modifications may be suitable. Indeed, the passageways 10 shown in Figures 3a-3f and described herebelow are not limited to passageways formed between arteries and veins, but may be broadly applicable to all passageways 10 of the present invention.

As shown in Figures 3a, the passageways 10 of the present invention may comprise unstented, unlined, interstitial tunnels (Fig. 3a). Alternatively, as shown in Figures 3b-3f, such passageways 10 may be provided with various types of surface modifications or ancillary apparatus, such as tubular linings (Fig. 3b), longitudinal constraining clips (Fig. 3c), stents or stented grafts which are confined to the interior of the passageway 10 (Fig. 3d), or stents or stented grafts which protrude out of and beyond the passageway 10 (Figs. 3e-3f).

Referring specifically to Figure 3a, there is shown a passageway 10 which extends between two blood vessels and which is devoid of any stent, liner, tubing, coating, valve, surface modification, substance or apparatus disposed within the passageway 10. In this regard, this unstented, unlined, unmodified passageway 10 is simply an interstitial tunnel (e.g., a puncture tract or tunnel) which extends between two blood vessels such that blood may flow from the lumen of one blood vessel into the lumen of the other.

Figure 3b shows a passageway 10 formed between two blood vessels and having a tubular inner lining 20 disposed therewithin. Such inner lining 20 may comprise a segment of rigid or flexible plastic tubing, a layer of a biocompatible polymeric coating, a layer of cells of a type which differs from that of the surrounding tissue (e.g., endothelial layer biological tissue graft, etc.), a layer of tissue of modified density as may be formed by laser treatment, electrocautery, etc., or any other type of matter which differs from the inner surface of the unstented and unlined passageway 10 itself. Such lining 20 within the passageway 10 may serve to a) facilitate laminar and non-turbulent blood flow through the passageway 10 or b) prevent unwanted closure of the passageway due to natural contraction of surrounding muscle or tissue ingrowth into the passageway 10. In

instances wherein the lining 20 is formed by application of a flowable material or energy (e.g., a chemical substance to produce a controlled chemical burn of the tissue or a biocompatible polymer coating, a suspension of endothelial cells, etc...) to the walls of the passageway 10, the application of such flowable material to the wall(s) of the passageway 10 may be accomplished through the use of a device such as that shown in Figures 8h-8h'' and discussed more fully herebelow, in reference to the devices of the present invention.

Figure 3c shows a passageway 10 wherein a longitudinal constraining apparatus 22 has been positioned so as to longitudinally compress the opposite ends of the passageway 10 toward one another, thereby compacting any tissue (e.g., loose connective tissue) which is located between the blood vessels. Such longitudinal constraining apparatus 22 may also be constructed to provide radial support for, and/or maintain patency of the passageway 10. The application of longitudinal compression to the passageway 10 by a constraining apparatus 22 may be particularly important in applications of the invention wherein the blood vessels which the passageway 10 connects are located on the surface of an organ (e.g., epicardially located coronary artery and vein), or are otherwise located such that cavernous or loose tissue (e.g., loose connective tissue) or open space exists between the artery and vein. The presence of such cavernous or loose tissue may allow blood which flows through the passageway 10 to infiltrate into such tissue or space between the artery and vein, as may result in the formation of a hematoma. Examples of specific types of constraining apparatus 22 which may be utilized to longitudinally compress the blood flow passageway 10 as shown in Figure 2c, or to otherwise facilitate coupling of two blood vessels by side-to-side anastomosis, are shown in Figures 9a-9f, and are



described more fully herebelow with reference to Figures 9a-9f.

Figure 3d shows a passageway 10 of the present invention having a non-protrusive stent or stented graft 24 positioned within the passageway 10. Such stent or stented graft 24 may comprise a pressure-expandable or self-expanding cylindrical stent or frame work, and may optionally be covered by a continuous tubular member such as a pliable segment of woven polyester or expanded polytetrafluoroethylene (ePTFE) the disposition of such stent or stented graft 24 within the passageway 10 may serve to hold the passageway 10 in a substantially open configuration to facilitate non-turbulent blood flow through the passageway 10. The stent or stented graft 24 may be formed of any suitable material including, but not necessarily limited to, various types of pressure expandable or self-expanding wire mesh or interwoven strands of polymeric material. In instances where a stented graft 24 is utilized, the tubular graft covering on the stented graft 24 may be continuous or may be partial, such that only a portion of the stent is covered.

It will be appreciated that when a protrusive stented graft (e.g., covered stent 26 or 28) is utilized, it may be unnecessary to additionally position the optional embolization members 12 within the lumen of the blood vessel into which the stented graft 26, 28 extend, as the tubular outer covering on the stented graft will serve to define a closed flow conduit through the lumen of that blood vessel and will substantially block the flow of endogenous blood through that portion of the blood vessel, thereby obviating any need for separate embolization members 12.

Figure 3d' shows modifications of the stent or stented graft 24a to include a flange 25 and/or perpendicular projections 27 extending from one or both end(s) of the stent or stented graft 24a to hold the

stent or stented graft 24a in substantially fixed longitudinal position within the passageway 10.

Figure 3e shows a hemiprotrusive or protrusive stent or stented graft 26 which may be constructed in the same manner as the non-protrusive stent or stented graft 24 shown in Figure 3d, but which differs from that shown in Figure 3d in that it protrudes or extends beyond the ends of the passageway 10, into adjacent portions of the artery A and vein. When so deployed, this stent or stented graft 26 will generally assume an "S" configuration, as shown in Figure 3e, to facilitate laminar, non-turbulent flow of blood in the desired direction through the passageway 10. The dotted lines on Figure 3e illustrate a "hemiprotrusive" embodiment of the stent or stented graft 26 wherein one end thereof is flush with one end of the passageway 10, while the other end thereof extends into the anatomical structure (i.e., vein) adjacent that end of the passageway 10. Such "hemiprotrusive" embodiment of the stent or stented graft 26 may be employed so as not to obstruct any available blood flow through the artery A, and will be particularly applicable in patients in whom the obstruction OB is not complete, and in whom some arterial blood flow continues to pass through the artery A. In other patients wherein the obstruction OB is complete, it may be appropriate to use the full "protrusive" embodiment of the stent or stented graft 26 wherein such stent or stented graft 26 extends out of both ends of the passageway 10 into the adjacent anatomical structures (i.e., vein and artery), as indicated by the dotted lines on Figure 3e.

Figure 3f shows another protrusive stent or stented graft 28 which extends fully through a first blood flow passageway 10a and an optional second blood flow passageway 10b, and which additionally protrudes through adjacent portions of the artery A and vein V, thereby forming a continuous "U"-shaped conduit through which

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laminar, non-turbulent blood flow may pass through both passageways 10a, 10b.

It will be appreciated that one or more valves may also be formed within any embodiment of the stent or stented graft 24, 26, 28 or within a tubular lining 20, or within a longitudinal constraining apparatus 22, or otherwise within the passageway 10, to facilitate the flow of blood in a desired direction(s) through the passageway(s) 10 while deterring or preventing blood from backflowing through the passageway(s) 10 in direction(s) opposite the desired direction(s).

iv. Transvascular Approaches for Forming the Passageway(s) Between Two Blood Vessels

Figures 4a-4e and the following detailed description, are provided for the purpose of illustrating some approaches which may be utilized for forming extravascular passageways 10 between two blood vessels, to accomplish certain revascularization methods of the present invention. The showings of Figures 4a-4e and the following detailed description are not intended to exhaustively illustrate all possible approaches which may be utilized for forming such passageways 10, but rather are provided as mere examples of presently perceived approaches for such procedures. Furthermore, although the showings of Figures 4a-4e illustrate applications wherein an obstruction OB is present within one of the blood vessels, the general approach is illustrated in these figures may be applicable to various revascularization methods wherein the passageways 10 are formed for purposes other than bypassing obstructions, or wherein the obstructions OB are located remotely from the locations at which the passageway(s) 10 are formed. Furthermore, it is to be appreciated that the approach is illustrated in Figures 4a-4c need not necessarily be performed between two blood vessels or between an artery and vein. Indeed, these approaches may be applicable between any blood vessel and any other hollow anatomical

structure, and may be useable for vein to vein, artery to artery or vein to artery passageway(s) 10.

Figure 4a shows one type of approach wherein a catheter 100 is advanced transluminally into an artery A and a tissue-penetrating element 102 is passed from the catheter 100 to form a first passageway 10a through the wall of the artery A, through a tissue located between the artery A and vein V, and through the wall of the vein. After the first blood flow passageway 10a has been created in this manner, a guide wire may be passed through the tissue-penetrating element 102 or through the catheter 100, and through the newly-created first passageway 10a. Thereafter, the tissue penetrating element is deactivated (e.g., retracted into the catheter 100), and the catheter is advanced over the guide wire, through the first passageway 10a, and into the lumen of the vein, past the site of the obstruction OB in the adjacent artery A. Thereafter, with the distal portion of the catheter positioned within the lumen of the vein, the tissue penetrating element 102 is once again advanced out of the catheter 100 to form a second blood flow passageway 102 which extends through the wall of the vein, any tissue located between the vein and artery A, and through the wall of the artery A. Thereafter, the tissue penetrating element 102 may be once again retracted into the catheter 100 and the catheter may be retracted from the vasculature and out of the body. In this manner, the approach shown in Figure 4a, accomplishes formation of a first blood flow passageway 10a upstream of the arterial obstruction OB and a second blood flow passageway 10b downstream of the arterial obstruction.

Figure 4b shows an alternative approach wherein a catheter 100 is transluminally advanced into the lumen of a vein, and the distal end of the catheter is positioned adjacent the location at which the first blood flow passageway 10a is to be created. Thereafter, the tissue

Figure 4c shows another alternative approach wherein a catheter 100 is transluminally advanced into an artery A, and the distal end of the catheter 100 is positioned adjacent the site at which the first blood flow passageway 10a is to be formed. Thereafter, the tissue-penetrating element 102 is passed out of the catheter 100 to form the first blood flow passageway 10a through the wall of the artery, any tissue between the artery A and vein V, and through the wall of the vein V. Thereafter, the tissue penetrating element 102 is deactivated (e.g., retracted into the catheter 100) and the catheter is further advanced through the lumen of the artery A and is passed through the obstruction OB until the distal end of the catheter 100 is located adjacent the site at which

Figure 4c shows another alternative approach wherein a catheter 100 is transluminally advanced into an artery A, and the distal end of the catheter 100 is positioned adjacent the site at which the first blood flow passageway 10a is to be formed. Thereafter, the tissue-penetrating element 102 is passed out of the catheter 100 to form the first blood flow passageway 10a through the wall of the artery, any tissue between the artery A and vein V, and through the wall of the vein V. Thereafter, the tissue penetrating element 102 is deactivated (e.g., retracted into the catheter 100) and the catheter is further advanced through the lumen of the artery A and is passed through the obstruction OB until the distal end of the catheter 100 is located adjacent the site at which

the second blood flow passageway 10b is to be formed. Such advancement of the catheter 100 through the obstruction OB will typically require that a guide wire be initially advanced through the obstruction OB to facilitate subsequent advancement of the catheter 100 through the obstruction OB. Such initial passage of a guide wire through the obstruction OB may be accomplished in cases where the obstruction OB is partial, or where the obstructive material is soft enough to permit a guide wire to penetrate therethrough. However, in cases where the obstruction OB is complete or formed of calcified plaque or other hard matter, the approach shown in Figure 4c may be less than viable and the operator will typically opt for one of the approaches shown in Figures 4a or 4b in such cases. However, in cases where the catheter 100 has been successfully advanced through the obstruction OB as shown in Figure 4c, the tissue penetrating element 102 will then be once again advanced out of the catheter 100 to create the second blood flow passageway 10b through the wall of the artery 10a, any tissue between the artery A and vein V, and through the wall of the vein V. Thereafter, the tissue-penetrating element 102 will be deactivated (e.g., retracted into the catheter 100) and the catheter will be extracted from the arterial vasculature and removed from the body. In this manner, the approach shown in Figure 4c accomplishes formation of a first blood flow passageway 10a and second blood flow passageway 10b in accordance with the present invention.

Figure 4d shows another alternative approach wherein a catheter 100 is provided with a positive pressure pumping 104 for pumping positive pressure fluid (e.g., saline solution) through the catheter and out of a plurality of positive pressure outlet apertures 106 formed in the body of the catheter 100 near the distal end thereof. A proximal sealing member 108 (e.g., a balloon which completely blocks the blood vessel lumen)

is formed on the catheter, proximal to the positive pressure outlet apertures 106. A separate distal sealing (e.g., a balloon) 110 is placed within the lumen of the vein V, slightly upstream of the site where the second blood flow passageway 10b is to be created. The catheter 100 is advanced through the lumen of the vein V until the distal end of the catheter is positioned adjacent the site of at which the second blood flow passageway 10b is to be created. Thereafter, the proximal sealing member 108 is deployed (e.g., inflated) so as to completely seal the vein V proximal to the positive pressure outlet apertures 106 of the catheter 100. Thereafter, positive pressure fluid (e.g., saline solution) is passed through a lumen of the catheter and out of the positive pressure outlet apertures 106, to cause the pressure  $P_1$  within the vein V to become elevated and, preferably, substantially equal to the mean pressure  $P_2$  within the artery A. Such pressurization of the lumen of the vein V provides a viable method of identifying the presence of any venous side branches SB which may require ligation, closure or embolization so as to prevent any significant steal of blood from the newly-created venous bypass conduit. Additionally, such pressurization of a lumen of the vein V may be maintained while the tissue-penetrating element 102 is advanced out of the catheter 100, through the wall of the vein V and through the wall of the artery A to form the passageway 10 of the present invention. Such equalization of the pressure  $P_1$  within the vein V to the pressure  $P_2$  within the artery also serves to prevent any rapid gush or flow of blood from the lumen of the artery A into the lumen of the vein V when the passageway 10 is created.

Figure 4e shows another alternative approach wherein a first catheter 100 is advanced into the artery A, and a second catheter 100 is advanced into the vein V. In some instances, the first and second catheters 100 will be advanced in generally opposite directions, as shown in

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the present invention may be oriented, aimed, controlled or guided.

Figure 5a shows one approach wherein an active imaging device 50 is positioned within the same blood vessel as the catheter 100 of the present invention. This active imaging device 50 may comprise any suitable type of catheter borne imaging device, including, but not limited, to an intravascular ultrasound apparatus (IVUS catheter), a Doppler apparatus, an angioscope, etc. In many instances, the active imaging device 50 will have a sensor (e.g., ultrasound transducer, sonic transducer, form image-receiving lens, etc.) formed at a specific location thereon. It will typically be desirable for such sensor 52 to be located immediately adjacent the location at which the tissue-penetrating element 102 is to enter the blood vessel wall in order to provide the desired observation, aiming and guidance of the tissue-penetrating element 102. It will be appreciated, that the active imaging device 50 may be mounted upon or formed internally of the passageway-forming catheter 100, may be carried within a monorail or sidecar formed on the catheter 100 (see Figs. 9-10), or may be located within a wholly separate and discreet catheter body, as is shown in Figure 5a. Embodiments of the a passageway-forming catheter device 100 which incorporate means for mounting of at least a distal portion of the active imaging device 50 within the passageway-creating catheter 100 are specifically shown in Figures 9-10, and are fully described herebelow with reference to such figures.

One alternative approach for observing, aiming and guiding the tissue-penetrating element 102 is shown in Figure 5b, wherein the active imaging device 50 is positioned within the blood vessel into which the tissue-penetrating element 102 of the, passageway-creating catheter 100 will pass. As shown in Figure 5b, the sensor 52 of the imaging device 50 may be located immediately adjacent the site at which the passageway 10

is to be formed, such that the sensor 52 may aim and guide the tissue-penetrating element 102 as it extends from catheter 100, toward the sensor 52 of the active imaging device 50.

5        Figure 5c shows another alternative approach which incorporates the use of a secondary imaging apparatus 54 (e.g., a passive or co-active apparatus) in addition to the primary active imaging device 50. This secondary imaging apparatus may be formed on the passageway-creating catheter 100, or on the tissue-penetrating  
10        element 102 itself, and is capable of communicating with or being sensed by the preliminary imaging apparatus 50. The primary imaging device 50, having a sensor 52 located thereon is positioned in the blood vessel adjacent that  
15        in which the passageway-creating catheter 100 is located. The active imaging device 50 will sense or communicate with the secondary imaging apparatus 54 so as to provide direct means for observing, aiming and guiding the tissue-penetrating element 102. In this embodiment, the  
20        secondary imaging apparatus 54 may comprise any suitable type of substance or apparatus which is interrogable, imageable, or otherwise discernable by the active imaging device 50. For example, the sensor 52 of the active imaging device 50 may comprise a radio frequency  
25        transmitter and the secondary imaging apparatus 54 on the passageway-creating catheter 100 may comprise a radio frequency transponder which may be interrogated by, and will emit a responsive signal to, a radio signal emitted by the radio frequency transmitter of the active imaging  
30        device 50. Alternatively, in embodiments where the active imaging device 50 is a fluoroscope, intravascular ultrasound (IVUS) device or Doppler, the secondary imaging apparatus 54 on the passageway-forming catheter 100 may comprise a radio opaque marker, reflective  
35        surface or sounding aperture from which radiation, sonic or ultrasonic energy may be reflected back to the active imaging device 50. Examples of the types of sounding

apertures or surfaces which may be formed on the body of the catheter 100 or tissue-penetrating element 102 to enhance visualization thereof by an active imaging device 50 are described in United States Patent No. 4,977,897 (Hurwitz).

Figure 5d shows a system wherein magnets 57a, 57b are mounted within modified passageway-forming catheters 101a, and are used in conjunction with a tissue-penetrating guide wire 103 having a sharpened distal tip 107, to form a passageway 10 between two blood vessels BV<sub>1</sub>, BV<sub>2</sub> as shown, each of the catheters 101a, 101b has a magnet 57a, 57b mounted in one side thereof. Each magnet, and adjacent inserts formed within the catheter body has a hollow lumen 109 extending therethrough. In this manner, the luminal openings in the magnets 57a, 57b may be positioned in direct alignment with one another, utilizing the attractive force of the magnets 57a, 57b to accomplish such aligned positioning. Thereafter, the tissue-penetrating guide wire 103 having the sharpened distal tip 107 may be advanced through the guide wire lumen 109a of the first catheter 101a and out of the luminal opening in the magnet 57a of that catheter 101a, through the wall of the first blood vessel BV<sub>1</sub>, through any tissue located between the first blood vessel BV<sub>1</sub>, and the second blood vessel BV<sub>2</sub>, through the wall of the second blood vessel BV<sub>2</sub> and into the luminal opening of the magnet 57b of the other passageway-forming catheter 101b. In this manner, the tissue-penetrating guide wire 103 will have formed a passageway 10 between the first blood vessel BV<sub>1</sub> and a second blood vessel BV<sub>2</sub>. It will be appreciated that the distal tip 107 of the tissue-penetrating guide wire 103 may comprise a sharp distal tip which is retractable into the guide wire such that the guide wire GW may remain within the blood vessels after the catheters 101a, 101b have been removed. Alternatively, the tissue-penetrating guide wire 103 may be a laser wire, hot wire or any other type of tissue-

penetrating member suitable to form the desired passageway 10.

Figure 5e-5e''' show methods and apparatus whereby passive radiographically visible markers formed upon a passageway-forming catheter 100 of the present invention, may be utilized to effect precise rotational positioning of the catheter 100 prior to formation of each extravascular passageway 10. Figure 5e shows, in schematic fashion, a passageway-creating catheter 100 positioned within a first blood vessel  $BV_1$  with the intention of forming a passageway 10 in accordance with the present invention from the first blood vessel  $BV_1$  into an adjacent target T (e.g., a body cavity, mass of tissue or another blood vessel). A radiographic imaging apparatus 118 such as a fluoroscope or x-ray device is utilized to provide a radiographic image of the first blood vessel  $BV_1$  and second blood vessel  $BV_2$  on a screen 120 (e.g., an x-ray cassette or fluoroscopy screen).

Figure 5e' shows a catheter 100 having radiographically visible (e.g., radio-opaque or radio-lucent) markers 122a, 122b formed at longitudinally spaced apart locations on opposite sides of the catheter 100. These radiographically visible markers 122a and 122b are preferably at equivalent elevational positions relative to the height H of the catheter 100, but are spaced apart longitudinally, as shown. Thus, precise rotational positioning of the catheter 100 may be achieved by causing these radiographically visible markers 122a, 122b to become directly aligned on the screen 120 at equivalent elevational positions, as shown in the lower side box of Figure 5e'.

Figure 5e'' shows another type of passive marking system which may be utilized to achieve precise rotational positioning of the catheter 100. With reference to Figure 5e'', the passageway-forming catheter 100 has a circular radiographically visible marking 124 on one side and a disk or dot shaped radiographically

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magnetic field created by the MRI system. In this manner, each movement of the catheter 100 within the MRI field will result in a change in current, phase and amplitude. The current phase and amplitude information received from the coil 134a may then be utilized to determine the precise location of the coil 134a relative to the target T. Moreover, if the coil 134a becomes located out of the specific plane which is being imaged by the MRI scanner 135, such will indicate the catheter 100 has been longitudinally moved out of the desired plane. In this manner, the coil 134a may be utilized for precise longitudinal, and rotational orientation of the catheter 100. Moreover, the information received from the coil 134a may be utilized to determine the exact distance between the coil 134a and the target T thereby providing information which will enable the operator to control the tissue-penetrating element 102 in a manner consistent with the length of the passageway 10 to be formed.

With specific reference to Figure 5g'', an alternative MRI marker 134b comprises a discrete mass of material which differs from the material of the catheter body 100, and which is visible on MRI. In this manner, the MRI-visible marker 134b may be precisely viewed on the MRI image, and may be utilized to visually adjust the longitudinal or rotational orientation and positioning of the catheter 100 relative to the target T. Moreover, the viewed distance between the marker 134b and the target T may be utilized to enable the operator to control the passage of the tissue-penetrating element 102 to create a passageway 10 of the desired length between the blood vessel BV<sub>1</sub> within which the catheter 100 is located and the target T.

Examples of specific types of "active" imaging apparatus which may be associated with, mounted upon or incorporated into the passageway-forming catheter 100 to

facilitate precise rotational orientation of the catheter 100 within a blood vessel, are shown in Figures 5h-5l.

With reference to Figure 5h, one type of active imaging apparatus which may be associated with, mounted upon or incorporated into the passageway-forming catheter 100 is a Doppler apparatus 136, such as that which is incorporated in a commercially available devices known as the Smart Needle, Cardiovascular Dynamics, Inc., Sunnyvale, California.

With reference to Figure 5h, the Doppler apparatus 136 is mounted upon or within the catheter 100 and is aimed or directed in a lateral direction (e.g., perpendicular to the longitudinal axis of the catheter 100). The Doppler apparatus 136 is useable to locate and discern a flow of fluid or other matter within the target T. Thus, the embodiment shown in Figure 5h is usable when target T comprises a blood vessel or other anatomical structure wherein fluid or other matter is flowing. The amplitude of the signal provided by the Doppler apparatus 136 and other information discernable therefrom enables the operator to a) longitudinally position the catheter such that the Doppler apparatus 136 is imaging the desired flow characteristics with in the target T (e.g, downstream of an obstruction and an artery), b) rotationally orient the catheter such that the amplitude of the Doppler signal is peaked so as to indicate that the Doppler apparatus 136 is precisely aimed at the center of flow within the target T (e.g., the center of the lumen in a blood vessel) and c) determine the distance between the Doppler apparatus 136 and the center of flow within the target T. Such determination of the distance between the Doppler apparatus 136 and the center of flow (e.g., lumen center) within the target T will enable the operator to control the tissue-penetrating element 102 such that the tissue-penetrating element 102 will pass or extend only the desired distance from the catheter 100, thereby forming

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Figure 5j illustrates the manner in which a first transmitter/receiver wire 140a and a second transmitter wire 140b may be utilized to accomplish precise rotational orientation of the passageway-forming catheter 100. As shown, the first transmitter or receiver wire 140a is positioned on or within the wall of the passageway-forming catheter 100 at a specific location, on one side of the catheter 100. The location of this first transmitter or receiver wire 140a is preferably immediately adjacent the location at which the tissue-penetrating element 102 will exit the catheter 100. A second transmitter or receiver wire 140b is positioned within the target T (e.g., second blood vessel, target tissue or other location into which the tissue-penetrating element of the passageway-forming catheter 100 is to be passed). After the catheter 100 has been advanced into the first blood vessel  $BV_1$ , the catheter will be rotated while a signal is emitted from one transmitter or receiver wire 140a, 140b such that such signal may be received by the other transmitter or receiver wire 140a, 140b. In this manner, the catheter may continue to be rotated until the amplitude of the signal received by the receiving transmitter/receiver wire 140a, 140b is peaked, thereby indicating that the first transmitter/receiver wire 140a and second transmitter receiver wire 140b are at their closest point, thereby indicating that the catheter 100 has been positioned in its desired rotational orientation within the first blood vessel  $BV_1$ . Additionally, one or both of the receiver wires 140a, 140b may be positioned in the respective blood vessel  $BV_1$  and/or target area T to effect the desired longitudinal positioning of the catheter 100 within the blood vessel  $BV_1$ , when the monitored signal between the wires 140a, 140b so indicates.

Figure 5k shows alternative arrangement wherein induction coil 142 is formed upon or within the wall of

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the passageway-forming catheter 100 at a specific location which corresponds to the site from which the tissue-penetrating element 102 will exit the catheter 100. A transmitter wire 144 is positioned within the target T (e.g., second blood vessel, target tissue or other location into which the tissue-penetrating element 102 of the catheter 100 is intended to pass) the transmitter wire 144 is energized so as to emit an electromagnetic signal and the induction coil 142 is also energized. Thereafter, the catheter 100 is rotated until the phase and amplitude of the signal within the induction coil 142 indicates that the induction coil 142 is at its closest point to the transmitter wire 100, thereby confirming that the catheter 100 has been placed in its appropriate rotational orientation to cause the tissue-penetrating element 102 to pass from the catheter 100, through the wall of the first BV<sub>1</sub>, and into the target T.

Figure 51 illustrates the manner in which first and second magnets 146a-146b may be utilized to effect precise rotational orientation of the passageway-forming catheter 100. The first magnet 146a is positioned on or within the wall of the passageway-forming catheter 100 at a specific location which corresponds to the site from which the tissue-penetrating element 102 will exit the catheter 100. The second magnet 146b is positioned on a second catheter 148 which is inserted into the target T (e.g., second blood vessel, target tissue or other location into which the tissue-penetrating element 102 is to be passed). The passageway-forming catheter 100 is then rotated, or is allowed to auto rotate) until the first magnet 146a and second magnet 146b are in alignment with and as close as possible to one another, thereby indicating that the passageway-forming catheter 100 has been placed in its correct rotational orientation to cause the tissue-penetrating element 102 to pass through

the wall of the first blood vessel  $BV_1$  and into the target T.

## B. Devices of the Present Invention

Figures 6 through 12 show devices of the present invention which are useable to form extravascular passageways 10 in accordance with the present invention, or to otherwise modify or equip such passageways 10. It is to be appreciated that the showings of Figures 6-12 and the detailed descriptions set forth herebelow are intended to describe and illustrate certain examples and presently preferred embodiments of the devices only, and are not intended to exhaustively list and describe all possible devices or embodiments in which the present invention may take physical form.

15           i.   Exit Schemes For Facilitating Passage of the  
              Tissue-Penetrating Element Out of the Catheter  
              Body

Figures 6a-6i show examples of arrangements and apparatus whereby a tissue-penetrating element 102 useable to initially form an extravascular passageway 10 of the of the present invention, may be passed out of a passageway-forming catheter 100 positioned within the lumen of a blood vessel such that the tissue-penetrating element 102 will pass through the wall of the blood vessel in which the catheter 100 is positioned, so as to create the desired extravascular passageway 10.

The detailed description of Figures 6a-6i set forth herebelow makes reference to various types of tissue-penetrating elements 102. The term "tissue-penetrating element" as used herein is intended to encompass all possible types of elongate members which may be utilized to penetrate tissue, devices or apparatus which may be utilized to penetrate tissue, or flows of energy (e.g., heat, laser beam, etc.) which may be used to penetrate tissue. Thus, when it is stated that the tissue-penetrating element 102 is "passed" out of the catheter 100, such statement shall not necessarily imply the

passage of a solid element from the catheter body, but may also include the operation of a tissue-penetrating apparatus or the passage of a flow of energy (e.g., heat, laser) from the catheter body in a manner and direction which will create the desired extravascular passageway 10. Furthermore, it shall be appreciated that the showings of Figures 6a-6i and the description provided in conjunction with such figures is not intended to describe or illustrate all possible arrangements or apparatus by which the tissue-penetrating elements 102 may be passed out of the passageway-forming catheters 100 of the present invention. Additionally, the following detailed description makes reference to some tissue-penetrating elements 102 which comprise a "pre-bent resilient member". The term "pre-bent resilient member" shall mean a member which when unconstrained will assume a curved or curvilinear configuration but which is sufficiently flexible to be withdrawn into and constrained by a lumen of the catheter device 100 without causing plastic deformation of the member. Examples of materials which may be utilized to form the pre-bent resilient members useable to form some of the tissue-penetrating elements 102 of the present invention include materials which are resilient, elastic or superelastic at body temperature and within the range of other temperatures under which the device will be utilized. Examples of these materials include some stainless steels, some plastics, and certain superelastic metal alloys and polymers such as nickel titanium alloys.

Figure 6a shows an embodiment of the passageway-forming catheter 100a wherein a lumen 112a extends longitudinally through the catheter 100a and terminates distally in a distal end aperture 114. The tissue-penetrating element 102 comprises a pre-bent, resilient member, as defined hereabove. When retracted within the lumen 112, this embodiment of the tissue-penetrating element 102 assumes a substantially straight, non-bent or

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minimally bent configuration in conformance to the surrounding wall of the catheter 100a. However, when the tissue-penetrating element 102 is advanced out of the outlet aperture 114a in the distal end of the catheter 100a, the tissue-penetrating element 102 will assume its pre-bent configuration such that the distal end of the tissue-penetrating element 102 will penetrate through the wall of the blood vessel wherein the catheter 100a is positioned. It is to be appreciated with respect to this embodiment, and all other embodiments of the invention herein described, that the tissue-penetrating element 102 may be configured to form any desired shape and size of passageway 10. Thus, in embodiments wherein the tissue-penetrating element 102 comprises a pre-bent resilient member, the pre-bent configuration of the tissue-penetrating element may be continuous curvilinear, partially straight and partially curvilinear, multicurvate, or any other pre-bent configuration which is suitable to form the initial extravascular passageway 10 of the desired size and shape. Furthermore, as described in more detail herebelow, various passageway modifying devices may be utilized to debulk, enlarge, dilate or otherwise modify the size and/or shape of the passageway such that the resultant final shape of the passageway 10 may differ substantially from that which is initially created by the first penetration of the tissue-penetrating element 102.

Figure 6b shows a passageway-forming catheter device 100b having a lumen 112 extending longitudinally therethrough and terminating distally in a side wall outlet aperture 114b. A deflector surface 115 is formed within the lumen 112b, between the side wall aperture 114b, and the contralateral surface of the lumen 112b. A tissue-penetrating element 102 formed of pliable material is of a substantially straight configuration when retracted within the lumen 112b. However, when advanced in the distal direction, the distal end of this

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advanced out of the distal end opening 114d of the catheter, the distal tip of the tissue-penetrating element 102 will abut against the deflector surface 186 of the anvil member 180, and will be thereby deflected, guided or caused to bend or curve in the lateral direction, such that the tissue-penetrating element will pass through the wall of the blood vessel BV, as shown.

Preferably, the deflector surface 186 of the anvil member 180 is not continuous with the inner surface of the lumen 112d of the catheter 100d.

Figure 6e shows another embodiment of the catheter device 100e wherein the catheter device 100e comprises a retractable outer catheter sheath 190, and an elongate inner member 192 having a pre-bent, resilient tube 194 formed within or mounted within the distal portion thereof. The elongate inner member 192 has a blunt distal tip 196 and an elongate side opening 198 formed therein, such that when the outer catheter sheath 190 is retracted in the proximal direction, the pre-bent resilient tubular member 194 will spring outwardly to its pre-bent, laterally-curved configuration, as shown. The tissue-penetrating element 102 of this embodiment may be a pliable member or a pre-bent resilient member which will assume a pre-bent configuration when advanced out of the distal end opening 114e formed in the distal end of the inner tube member 194. In this manner, the pre-bent tube member 194 may form a first angle,  $A_1$  when the catheter sheath 190 is retracted in the proximal direction, and the pre-bent, resilient tissue penetrating element 102 may form an additional second angle  $A_2$  when it is advanced out of the distal end opening 114e of the pre-bent tube member 194, such that the first angle  $A_1$  and second angle  $A_2$  will combine to form a resultant third angle  $A_3$  between the direction in which the distal tip of the tissue-penetrating element 102 is aimed and the longitudinal axis LA of the catheter 100e. As explained in detail hereabove, the angle  $A_3$  between the direction



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Figure 6g shows yet another embodiment of a passageway-forming catheter device 100g comprising a

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tubular catheter body having a hollow lumen 112g extending longitudinally therethrough and opening distally through a distal end opening 114g. The distal end of the body of the catheter 100g is bendable in a lateral direction, as shown in the dotted lines of Figure 6g. Such bending of the distal end of the catheter device 100g in the lateral direction, will cause the outlet aperture 114g to become directed toward the wall of the blood vessel within which the catheter device 100g is positioned, such that subsequent advancement of the tissue-penetrating element 102 out of the distal end opening 114g of the catheter device 100g will cause the tissue-penetrating element 102 to contact and pass through the wall of the blood vessel BV within which the catheter device 100g is positioned. The bendable distal end of the catheter 100g may be caused to transition from its straight configuration to its curved or bent configuration by the presence of a shape memory alloy, a pull wire, opposing electromagnetic coils or any other suitable mechanism, apparatus or material known in the art for causing the tip of a catheter to bend.

Figure 6h shows yet another embodiment of a passageway-forming catheter device 100h comprising a tubular catheter 100h having a tissue-penetrating element 102 passable therefrom. An inflatable balloon 210 is formed on one side of the catheter device 100h, opposite the location at which the extra-vascular passageway 10 is to be formed in the wall of the blood vessel BV. Inflation of the balloon 210 prior to or during advancement of the tissue-penetrating element 102 will a) deter or prevent the catheter 100h from recoiling and pressing against the contralateral wall of the blood vessel BV as the tissue-penetrating element 102 is advanced through the wall of the blood vessel BV, and b) may operate to stabilize and hold the distal portion of the catheter device 100h in a substantially fixed position within the lumen of the blood vessel BV, so as

to permit the application of an enhanced force or pressure upon the tissue-penetrating element 102 as it is advanced or otherwise passed through the wall of the blood vessel BV. In the embodiment shown in Figure 6h, the catheter device has a distal end outlet opening 114h and the tissue-penetrating element 102 is a pre-bent resilient member which will assume a laterally bent or curved configuration as it exits the distal end opening 114h. It will be appreciated, however, that the side balloon 210 shown in Figure 6h may be incorporated and used in conjunction with any of the types of catheters show in Figures 6a-6i, including those wherein the tissue-penetrating element exits through a side-outlet aperture formed in the side wall of the catheter device 100h.

Figure 6i shows yet another embodiment of a passageway-forming catheter device 100i comprising an elongate, flexible, tubular catheter body having a hollow lumen 114i extending longitudinally therethrough and a blunt tip member 212 rotatably mounted on the distal end of the tubular catheter body. The distal tip member 212 has a curved lumen 214 extending therethrough, the proximal end of which is in alignment with the lumen 114i of the catheter 100i. and the distal end of which terminates in a side outlet aperture 114i formed on one side of the distal tip member 112. The tissue-penetrating element 102 in this embodiment may comprise a pliable member or a resilient pre-bent member. In either instance, the tissue-penetrating element 102 may be initially advanced to an intermediate position wherein the distal tip of the tissue-penetrating element is positioned within the curved lumen 214 of the distal tip member 212. With the tissue-penetrating element 102 in such intermediate position, the tissue-penetrating element 102 may be rotated. Such rotation of the tissue-penetrating element 102 will, due to its frictional engagement within the curved lumen 214 of the distal tip

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member 121, cause the distal tip member 212 to concurrently rotate. In this manner, partial advancement and rotation of the tissue penetrating element 102 may be utilized as a means for rotatably moving the distal tip member 212 to adjust the rotational orientation of the side outlet aperture 114i so as to direct the tissue-penetrating element in the desired lateral direction to form the extravascular passageway 10 of the present invention at the desired location. In this manner, further advancement of the tissue-penetrating 102 out of the side outlet aperture 114i, after the desired rotational orientation of the distal tip member 212 has been achieved, will cause the tissue-penetrating element to form the desired extravascular passageway 10 through the wall of the blood vessel BV within which the catheter device 100i is positioned.

ii. Types of Tissue-Penetrating Elements Which May Be Incorporated Into the Passageway-Forming Catheter

The following Figures 7a-7m and the accompanying detailed description set forth herebelow are intended to describe and illustrate some types of tissue-penetrating elements 102 which may be utilized in accordance with the present invention. It is to be appreciated and understood that the specific types of tissue-penetrating elements 102 described herebelow and shown in Figures 7a-7m are not intended to exhaustively list and explain all possible types of tissue-penetrating elements 102 which may be useable but, rather, are intended to provide examples of the types of tissue-penetrating elements 102 which may be utilized. As explained hereabove, the term "tissue-penetrating element" is not limited to solid members but may also include various devices, apparatus, or flows of energy. Furthermore, the term "resilient, pre-bent member" shall be interpreted in accordance with the definition of such term set forth hereabove.

With reference to Figures 7a-7m, there are shown various types of tissue-penetrating elements 102 which may be incorporated into the passageway-forming catheter 100 of the present invention. These tissue-penetrating elements 102 are designed to pass out of a flexible catheter body and to penetrate through the wall of the blood vessel within which the catheter 100 is located, and to adjacent extravascular tissue, as necessary, to form the desired extravascular passageway 10 of the present invention.

Figures 7a and 7a' show a first embodiment of a tissue-penetrating element 102a. This embodiment of the tissue penetrating element 102a comprises an elongate, pliable needle formed of a pliable material such as polyimide tubing of the type available commercially from MicroLumen, Inc., Tampa, Florida, and having a sharpened, beveled distal tip 300 formed thereon. An optional lumen 302 may extend longitudinally through the penetrating element 102a. A pre-bent, resilient member 304 is positioned longitudinally within the tissue-penetrating element 102a, or alternatively a pull wire.

When the element 102a is retracted within the lumen of the passageway-forming catheter 100, the resilient spine member 304a will be caused to assume a substantially straight or minimally bent configuration which conforms to the configuration of the catheter lumen and allows the tissue-penetrating element 102a to be fully retracted within the catheter lumen. However, when the tissue-penetrating element is exposed or advanced out of the passageway-forming catheter 100, a distal portion of the pre-bent spine member 304 will bend or curve in a lateral direction, thereby causing the entire, pliable tissue-penetrating element 102a to assume such laterally bent and curved configuration, as designated by the phantom lines on Figure 7a. In this manner, the pre-bent resilient spine member 304 will cause the pliable or flexible body of the tissue-penetrating element to assume

the desired laterally bent or curved configuration. In some instances, this arrangement may also allow the pliable body of the tissue-penetrating element 102a to be rotated or spun around the pre-bent resilient spine member 304a to facilitate or enhance advancement of the tissue-penetrating element through the blood vessel wall or adjacent tissue.

Figure 7b shows another embodiment of a tissue-penetrating element 102b which comprises a pliable elongate proximal shaft 306 having a rigid, sharpened distal tip member 308 mounted upon, or otherwise joined to the distal end of the proximal shaft 306. In this embodiment, the proximal shaft 306 of the tissue-penetrating element 102b is sufficiently pliable and bendable to navigate tortuous anatomical curves or curves within the lumen of a catheter, while the rigid distal tip portion 308 is formed of rigid material, such as stainless steel, so as to maintain a substantially sharp distal tip 310 which will penetrate and pass through the blood vessel wall and desired extravascular tissue, to form the extravascular passageway 10 in accordance with the present invention.

Figure 7c shows another embodiment of a tissue-penetrating element 102c which comprises an elongate solid or hollow needle having a sharpened distal tip 312, and formed of a pre-bent resilient material such as a superelastic nickel titanium alloy or other metal alloy which exhibits resilient, elastic or superelastic properties within the range of temperatures which the tissue-penetrating element 102c will encounter during normal use. This embodiment of the tissue-penetrating element 102c, being formed of pre-bent resilient material, will assume a substantially straight or minimally bent configuration when retracted into the lumen 112 of the passageway-forming catheter 100, such that the entire tissue-penetrating 102c may be retracted into the lumen 112. However, when the tissue-penetrating

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element 102c is advanced out of the outlet aperture 114c in the catheter 100, the tissue-penetrating element 102c will assume its pre-bent configuration so as to become curved or bent in the lateral direction at an angle A relative to the longitudinal axis LA of the catheter, thereby facilitating advancement of the distal portion of the tissue-penetrating element 102c through the blood vessel wall and through any adjacent tissue to form the desired extravascular passageway 10 in accordance with the present invention.

Figure 7d shows yet another embodiment of a tissue penetrating element 102d which comprises a hollow needle having a sharpened (e.g., beveled) distal tip 314 and a guide wire passage lumen 316 of extending longitudinally therethrough. It will be appreciated that this hollow needle may be formed of either pre-bent, resilient material or pliable material, in accordance with the various tissue-penetrating element exit schemes illustrated in Figures 6a-6i and described in detail hereabove. The embodiment of the puncturing element 102d shown in Figure 7d has the advantage of permitting a guide wire GW to be advanced through the guide wire passage lumen 316. In this manner, the guide wire GW may be periodically advanced in the distal direction or may be placed under continuous distally directed pressure such that, when the sharpened distal tip 314 of the tissue-penetrating element 102d enters the lumen of another blood vessel or another hollow cavity, the guide wire GW will rapidly advance in the distal direction, thereby signaling that the sharpened distal tip 314 of the tissue-penetrating element 102d has entered such blood vessel lumen or hollow cavity. Thus, this embodiment of the penetrating element 102d is particularly useable in the revascularization methods of the present invention wherein an extravascular passageway 10 is formed between two blood vessels, or in other extravascular procedures of the present invention wherein

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blood vessel lumen or other hollow body cavity, the outer sheath 326 may be advanced in response to intermittent or continuous distally directed pressure applied to the outer sheath 326. Such distally directed pressure may be applied manually or by way of a continuous pressure-exerting safety device of the type shown in Figures 10c', 10c'' and 10c''', as described fully herebelow.

Figure 7g shows yet another embodiment of a tissue-penetrating element 102g which comprises an elongate tubular member 328 having an energy emitting distal tip 330 formed on the distal end thereof. One or more energy transmission wires or members 332 may extend through the tubular member 328 and will be connected to the energy-emitting distal tip 330 so as to deliver the desired form of energy to the distal tip 330. In this manner, the energy-emitting distal tip may emit any suitable type of energy which will ablate, sever or facilitate advancement of the member 328 through a blood vessel and other extravascular tissue, in accordance with the methodology of the present invention. Examples of the types of energy which may be emitted from the energy-emitting distal tip 330 include heat (e.g., electrical resistance heat or laser heat to form a "hot tip"), monopolar electrocautery, bipolar electrocautery, ultrasound, etc.

Figure 7h shows yet another embodiment of a tissue-penetrating element 102h comprising an elongate flexible catheter 100 having a lumen 112 extending longitudinally therethrough and a rotatable passageway-forming tip 336 mounted on the distal end thereof. A rotatable drive member 338 extends longitudinally through the lumen 112 of the catheter 100, and operates to rotate the distal tip 336 when it is desired to advance the tissue-penetrating element 102h through the wall of a blood vessel or other tissue. The rotating distal tip 336 may be of any suitable configuration which, when rotated, will form a tunnel or passageway through tissue of the desired configuration. In this regard, the outer surface

of the rotatable tip 336 may be provided with a sharpened spiral blade or threaded member 337 or other suitable tissue-cutting or dilating apparatus to facilitate the rotational boring, cutting or dilation of tissue, desired  
5 of the rotatable tip 336.

Figure 7i shows yet another embodiment of a tissue-penetrating element 102i. In this embodiment, the tissue-penetrating element 102i comprises a beam of pulsed or continuous laser light which is projected out  
10 of an aperture or lens-covered port 114i formed in the catheter 100. A laser-transmitting element 340 such as a fiber optic extends longitudinally through the lumen 112 of the catheter 100, and terminates proximal to and in alignment with a reflective surface 341, such as a  
15 mirror, from which the laser light emanating from the distal end of the laser transmitting member 340 will be reflected out of the side aperture or port 114i. Thus, in this particular embodiment, the tissue-penetrating element 120i is not formed of solid matter or deployable  
20 tissue penetrating apparatus, but rather, comprises a pulsed or continuous beam of laser light capable of vaporizing or ablating the blood vessel wall and other extravascular tissue to form the desired extravascular passageway 10 of the present invention.

It will be appreciated that this embodiment of the tissue-penetrating element 102i may be modified in various ways. For example, in place of the reflective surface 341, a continuous energy guide (e.g., fiber optic) may extend through the catheter body and terminate  
30 in an outlet port or lens located on the side wall of the catheter, such that the flow of energy (e.g., laser light) will pass outward in the lateral direction from the catheter. Alternatively, an energy-emitting apparatus may be mounted on or within the side wall of  
35 the catheter so as to emit the desired flow of energy in a lateral outward direction from the catheter. Moreover, the embodiment specifically shown in Figure 7i and the

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above-mentioned variations thereof shall not be limited to laser energy, but may utilize any suitable flow of energy including heat, ultrasound, laser light, etc.

Figure 7j shows yet another embodiment of tissue-  
5 penetrating element 102j which may be incorporated into the passageway-forming catheters 100 of the present invention. In this embodiment, the tissue-penetrating element 102j comprises an elongate laser-transmitting member through which laser energy may be passed such that  
10 the laser energy will emanate out of the distal end 343 of the elongate laser-transmitting member 102j. The elongate laser-transmitting member 102j may be pre-bent such that if it is passed out of a distal end opening 114 in a catheter 100, it will automatically bend or curve in  
15 a lateral direction so as to contact the wall of the blood vessel BV within which the catheter 100 is located, to allow laser energy emanating from the distal end 343 of the laser-transmitting member 102j to form the desired extravascular passageway 10 in the wall of the blood  
20 vessel and other extravascular tissue. Alternatively, it will be appreciated that various other exits schemes may be utilized for the laser-transmitting member 102j, such as sidewall apertures formed in the catheter 100, in accordance with the suitable exits schemes for all  
25 tissue-penetrating elements 102 as illustrated in Figure 6a-6i and described fully hereabove.

Figure 7k shows yet another alternative embodiment of a tissue-penetrating element 102k usable in the passageway-forming catheters 100 of the present  
30 invention. The tissue-penetrating element 102k shown in Figure 7k comprises an elongate hollow needle having a lumen 316 extending longitudinally therethrough and having a sharpened distal tip. A vacuum source (e.g., suction) 344 is attached to the proximal end of the lumen  
35 316 of the tissue penetrating element 102k so as to draw or pull tissue into the lumen 316 as the distal end of the tissue-penetrating element is being advanced through

the wall of the blood vessel BV or other tissue through which the extravascular passageway 10 of the present invention is to be formed. An optional sealing cuff 317, which may comprise an inflatable annular balloon mounted about the exterior of the tissue-penetrating element 102k a spaced distance from the sharpened distal tip thereof, may be positioned in abutment with the wall of the blood vessel BV so as to form a seal which will prevent the suction applied to the lumen 316 from the leaking outwardly or aspirating blood from the lumen of the blood vessel BV. In this manner, the optional sealing cuff 317 may facilitate drawing or aspiration of the tissue of the blood vessel wall BV or other extravascular tissue into the distal end of the lumen 316 as the tissue-penetrating element 102k is advanced through the tissue of the blood vessel wall or other extravascular tissue.

Yet another embodiment of a tissue-penetrating element 102l useable in the passageway-forming catheters 100 of the present invention, is shown in Figure 71. With reference to Figure 71, there is provided a tissue-penetrating element 102l formed by the combination of a standard tissue-penetrating element 102 such as a solid or hollow needle having a sharpened distal tip, and a surrounding tubular sheath 346 having a resilient, pre-bent distal portion 347 and a hollow lumen 349 extending longitudinally therethrough. The sheath 346 having the tissue-penetrating element 102 mounted therewithin is advanced through the lumen 112 of the catheter 100. When the distal portion 347 of the sheath 346 is advanced out of the distal end opening 114 of the catheter 100, the pre-bent distal portion 347 of the sheath will automatically curve or bend in a lateral direction, as illustrated by the dotted lines on Figure 71. Thereafter, the pliable or pre-bent tissue-penetrating element 102 will be advanced through the lumen 349 of the sheath 346, and through the wall of the blood vessel BV or other extravascular tissue to form the desired

extravascular passageway 10 in accordance with the present invention. Optionally, a vacuum source 345 may be connected to the proximal end of the lumen 349 of the sheath 346 to draw the wall of the blood vessel BV into contact with the distal end of the distal portion 347 of the sheath 346, thereby facilitating efficient advancement and penetration of the tissue-penetrating element 102 through the blood vessel wall or other tissue.

Yet another embodiment of a tissue penetrating element 102m is shown in Figure 7m. With reference to Figure 7m, there is provided a catheter 100 having a side wall opening 114 formed therein and a hollow lumen 112 extending longitudinally therethrough, and terminating at side wall opening 114. A tissue-penetrating element 102, such as a sharp-tip hollow or solid needle, is advanceable through the lumen 112 of the catheter 100 and out of the side opening 114. A vacuum source 350 (e.g., suction) is attached to the proximal end of the lumen 112 and suction is applied, to draw the wall of the blood vessel BV downwardly and into contact with the side aperture 114, as shown in Figure 7m. Such suction-induced contact of the wall of the blood vessel BV with the side aperture 114 facilitates efficient advancement and penetration of the tissue-penetrating element 102 through the wall of the blood vessel BV, to create the desired extravascular passageway 10 in accordance with the present invention. Also, this suction attachment helps to hold the tissue which is being penetrated, in a taught state, thereby facilitating penetration of such tissue.

### iii. Passageway-Modifying Apparatus

Figures 8a-8h and the detailed description thereof set forth herebelow show various types of apparatus which may be utilized to treat, enlarge, debulk, dilate, line, coat or otherwise modify the extravascular passageway 10 initially formed by the tissue-penetrating element 102.

5

10

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such that the passageway modifying apparatus 500b may be advanced over a guide wire GW which has been inserted through the initial passageway or tract created by the tissue-penetrating element 102. As this passageway  
5 modifying apparatus 500b is advanced through such initially formed passageway or tract, the tapered distal portion 508 will dilate the passageway or tract to the enlarged diameter of the proximal portion 506 of the apparatus 500b. An optional energy-emitting band 510 may  
10 be mounted about the proximal portion 506 of the apparatus 500b, so as to emit heat or other energy to further modify the surface of the passageway 10 as the apparatus 500b is advanced therethrough.

Figure 8c shows a third embodiment of a passageway  
15 modifying apparatus 500c which comprises an elongate tubular member having an annular, sharpened distal cutting tip 512 which is similar to the distal cutting tip 502 of the embodiment shown hereabove in Figure 8a, but which is further adapted to emit energy (e.g, heat,  
20 vibration, laser light, etc.). In this embodiment of the apparatus 500c, an energy transition wire or member 514 extends through the tubular proximal portion of the apparatus 500c and is connected to the annular distal cutting tip 512 so as to transmit electrical energy,  
25 ultrasonic vibration, or any other suitable form of energy to the distal tip 512, to facilitate advancement of the distal tip 512 to the desired blood vessel wall or other extravascular tissue. The hollow lumen 504 formed through the apparatus 500c permits that apparatus 500c to  
30 be advanced over a guide wire which has been positioned within the initially formed passageway or tract created by the tissue-penetrating member. Electrical current or other energy will be passed through the energy transmitting wire or member 514 during advancement of the  
35 apparatus 500c, such that heat or other energy is emitted by the distal tip to facilitate passage and advancement of the apparatus 500c through the tissue. It will be

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102. A pull wire (not shown), or the guide wire itself may engage the distal portion 520'' of the catheter body such that the distal portion of the catheter body may be pulled in the proximal direction, thereby decreasing the gap between the proximal portion 520' and distal portion 520'' of the catheter body. This will cause the cutting wires 522 to bow outwardly, as shown by the phantom lines on Figure 8e. In operation, the apparatus 500e will be advanced over the guide wire GW and through the initially formed passageway or tract. Thereafter, the proximal portion 520'' of the catheter body will be drawn in the proximal direction to shorten the distance between the distal end of the proximal portion 520' and distal portion 520'' of the catheter body, thereby causing the cutting wires 522 to bow outwardly. Optionally, electrical current may be passed through the cutting wires such that the cutting action of the wires will be enhanced. Thereafter, the apparatus 500e will be withdrawn in the proximal direction through the initially formed passageway or tract created by the tissue-penetrating element 102, such that the outwardly bowed cutting wires 522 will enlarge the initially formed passageway or tract to thereby convert the passageway or tract into an enlarged slit-like extravascular passageway 10, in accordance with the present invention.

Figure 8f shows a sixth embodiment of a passageway-modifying apparatus 500f which comprises an elongate shaft member 530 having a pull-back cutting apparatus 532 mounted on the distal end thereof. The pull-back cutting apparatus 532 comprises a rigid member having a blunt distal surface 534 and an annular proximal cutting edge 536. A hollow lumen 504f extends longitudinally through the shaft 530 and pull-back cutting member 532 such that the apparatus 500f may be advanced over a guide wire GW which has been inserted in the initially formed passageway or tract created by the tissue-penetrating element 102. After the pull-back cutting member 532 has

been fully advanced into the initially-formed passageway or tract, it will be retracted in the proximal direction such that the proximal cutting surface 536 will cut away tissue so as to enlarge or debulk the passageway.

5 Optionally, the cutting surface 536 may be rotated during the retraction of the pull-back member 532 to facilitate cutting of the tissue. Also, optionally, an anvil (not shown) may be positioned at the opposite end of the passageway 10 to provide counter-pressure against the  
10 cutting edge 536, thereby facilitating the cutting of tissue by the pull back cutting member 532. Tissue which is severed from the wall of the passageway by the proximal cutting surface 536 will be collected within the interior chamber 538 of the pull-back cutting member 532.

15 Figure 8g shows a seventh embodiment of a passageway-modifying apparatus 500g which comprises an elongate shaft 540 having a push-forward cutting member 542 mounted on the distal end thereof. A hollow lumen 504g extends longitudinally through the shaft 540 and  
20 cutting member 542 such that the apparatus 500g may be advanced over a guide wire GW which has been inserted through the initially-formed passageway or tract created by the tissue-penetrating element 102. The cutting member 542 comprises a distal portion 542' having a  
25 generally cylindrical outer surface and a proximal portion 542'' having an outwardly tapered outer surface. A sharpened annular cutting edge 544 is formed on the distal end of the distal portion 542' such that, as the apparatus 500g is advanced in the distal direction, the  
30 cutting edge 544 will cut a generally cylindrical mass of tissue, to thereby enlarge the initially-formed passageway or tract through which the apparatus 500g is advanced. Optionally, the sharpened annular cutting edge 544 of the apparatus 500g may be rotated during the  
35 advancement of the apparatus 500g. Also, an optionally anvil (not shown) may be positioned at the opposite end of the passageway 10 to provide counter-pressure against

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the cutting edge 544, thereby facilitating the cutting of tissue by the apparatus 500g.

Figure 8h shows an eighth embodiment of a passageway-modifying apparatus 500h. Comprising an  
5 elongate tubular member 550 having a lumen 504h extending longitudinally therethrough. A plurality of outflow apertures 554 are formed in the tubular member 550, within a region which is a spaced distance from the distal end of the tubular member 550. Also, a distal  
10 guide wire outlet aperture is formed in the distal end of the member 550 such that the apparatus 500h may be advanced over a guide wire GW which has been inserted through an initially formed passageway or tract created by the tissue-penetrating element 502. Proximal and  
15 distal sealing balloons 552', 552'' are formed about the outer surface of the tubular member 550, proximal and distal to the outflow apertures 554. As show in Figure 8h'', the tubular member 550 may be advanced over the guide wire GW until the outflow apertures 534 are located  
20 within the passageway 10 which is to be treated with a flowable liquid substance. Thereafter, the annular sealing balloons 552', 552'' will be inflated so as to seal off the opposite ends of the passageway 10. Thereafter, the desired flowable substance will be passed  
25 through the lumen 504h of the tubular member 550 such that it will flow out of the outflow apertures 554 and will fill the interior of the passageway 10, which remains sealed by the sealing balloons 552', 552''. After the flowable material has effected the desired  
30 treatment of the walls of the passageway 10, negative pressure may be applied to the lumen 504h to withdraw the flowable material from the interior of the passageway 10. Thereafter, the sealing balloons 522', 522'' will be deflated and the apparatus 500h will be withdrawn and  
35 removed from the passageway 10. Figure 8h' shows an alternative modification the device 500h' wherein no liquid outflow apertures 554 are formed on the tubular

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member 550, but rather, an energy transmitting member (not shown) such as a wire will extend through the body of the tubular member 550 and the region of the tubular member 550 between the sealing balloons 552', 552'' will be equipped with an electrode, electrocautery apparatus, resistance heater, laser, or other energy emitting apparatus such that the outer surface of the tubular member 550 between the sealing balloon 552', 552'' will become heated or will otherwise emit energy to treat the walls of the passageway 10 when the apparatus 500h'' becomes positioned within the passageway, in the manner described hereabove with reference to Figures 8h and 8h''.

iv. Apparatus for Longitudinal Compression and/or Support of Extravascular Passageways Formed Between Two Blood Vessels

In those applications where the extravascular passageways 10 of the present invention are formed between two (2) blood vessels (as in many of the above-described revascularization procedures) the presence of cavernous or loose tissue between walls of the blood vessels may be problematic, in that blood flowing through the passageway 10 may tend to infiltrate into such cavernous or loose tissues, thereby giving rise to blood leakage and/or hematoma formation.

One means for deterring such infiltration of blood into tissue or space between the adjacent blood vessel walls is the placement of a longitudinal passageway compression apparatus 22 within the passageway 10 so as to compress such cavernous or loose tissue, thereby preventing infiltration of blood thereinto. Furthermore, the deployment of such longitudinal compression apparatus 22 within the passageway 10 may additionally provide structural support within the passageway so as to maintain the patency of the passageway and prevent the passageway from unwanted flexing or closure due to movement of the adjacent tissues. It will be

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appreciated, however, that any such longitudinal compression apparatus 22 will preferably be constructed so as to provide sufficient longitudinal compression to prevent the unwanted infiltration of blood into the adjacent tissues but will not cause over-compression of such tissues as could cause iatrogenic ischemia and possible necrosis of such tissues. Figures 9a-9f''' and the following detailed description of such figures are directed to examples of specific longitudinal compression apparatus 22 which may be positioned within extravascular passageways 10 of the present invention to prevent tissue infiltration of blood and/or to provide structural support within the passageway. It is to be understood that Figures 9a-9f''' and the following detailed description are not intended to exhaustively list and describe all possible types of longitudinal compression apparatus 22 which may be useable in accordance with the present invention. Rather, these figures and the following detailed description are mere examples of the types of longitudinal compression apparatus 22 which are useable therefore.

The utility of the longitudinal compression apparatus 22 shown in Figures 9a-9f''' and described herebelow is not necessarily limited extravascular passageways 10 of the present invention, but may also be useable in connection with other methods for forming side-to-side connections (e.g., anastomoses) between juxtapositioned tubular anatomical passageways of the body such as blood vessels, fallopian tubes, etc.

Figures 9a-9a' show a first embodiment of a longitudinal compression apparatus 22a which comprises a first annular member 600 and a second annular member 602, which are directly alienable with one another and connectable to one another so as to longitudinally compress the blood vessel walls and other tissue which surround the passageway 10 formed between two blood vessels  $BV_1$  and  $BV_2$ . The first ring member 600 has a

plurality of leg members 604 which extend from one side thereof. The second ring member 602 has a plurality of receiving apertures 606 which are positioned and configured to receive the leg members 604 therewithin.

5 Each leg members 604 has a bayonet connector 608 or other type of connector formed thereon such that, when the leg members 604 become inserted into the receiving apertures 606, the connector 608 will engage corresponding members or surfaces formed within the receiving apertures 606 so  
10 as to lock and hold the first and second ring members 600, 602 in a manner which causes longitudinal compression of the portions of the walls of blood vessels  $BV_1$  and  $BV_2$  and other intervening tissue which surrounds the passageway 10.

15 Figures 9b-9b''' show as second embodiment of a longitudinal compression apparatus 22b which comprises a resilient (e.g., superelastic) wire ring which has been bent into the configuration shown in Figure 9b having two upper arcuate segments 610', 610'' and two lower arcuate  
20 segments 612' and 612'', as shown. The apparatus 22b is initially mounted within the lumen 614 of a tubular catheter 616. An inner catheter member 618 having a reduced-diameter distal portion is coaxially positioned within the lumen 614 of the outer catheter 616, such that  
25 the longitudinally extended lower arcuate portions 612', 612'' of the apparatus 22b are captured and frictionally engaged between the outer surface of the distal reduced diameter portion of inner tubular catheter 618, and the inner luminal surface of the outer catheter 616, as shown  
30 in Figure 9b'. The outer catheter 616 is initially advanced through the passageway 10 wherein the apparatus 22b is to be deployed, and the inner catheter 616 is then advanced in the distal direction to push the longitudinally extended upper arcuate portions 610',  
35 610'' out of the distal end opening of the catheter 616, such that the upper arcuate portions 610', 610'' will resiliently bend outwardly so as to become positioned

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upon the luminal surface of the first blood vessel  $BV_1$ .  
Thereafter, the inner catheter 618 is drawn backwardly to  
release the longitudinally extended lower arcuate  
portions 612, 612', 612'' form frictional engagement and  
5 capture between the inner tubular catheter 618 and outer  
tubular catheter 616, and the outer tubular catheter 616  
is withdrawn such that the lower arcuate portions 612',  
612'' will pass out of the open distal end of the  
catheter 616 and will resiliently bend outwardly so as to  
10 abut against and engage the luminal surface of the second  
blood vessel  $BV_2$ , thereby compressing the walls of the  
blood vessels  $BV_1$  and  $BV_2$  and the cavernous or loose  
tissue positioned therebetween, in the manner illustrated  
in Figure 9b. The circular wire member of which the  
15 apparatus 22b is formed may be any suitable resilient  
type of material, and preferably may comprise a nickel-  
titanium alloy or polymer which exhibits superelasticity  
or high flexural properties within the range of  
temperatures which will be encountered by the apparatus  
20 22b during deployment and implantation within the  
mammalian body.

Figure 9c shows a third embodiment of a longitudinal  
compression apparatus 22c comprising a first toroidal  
balloon 620 and a second toroidal balloon 622. The first  
25 and second toroidal balloons 620, 622 are positioned in  
longitudinal alignment with one another and are joined by  
a plurality of longitudinal connector members 624. The  
apparatus 22c is initially positioned within the  
passageway such that the deflated first toroidal balloon  
30 620 is positioned adjacent the luminal surface of the  
first blood vessel  $BV_1$  and the deflated second toroidal  
balloon 622 is positioned adjacent the luminal surface of  
the second blood vessel 622, with the connector members  
624 extending longitudinally through the passageway 10.  
35 Thereafter, the first and second toroidal balloons 620,  
622 are inflated so as to longitudinally compress the  
portions of the walls of the blood vessels  $BV_1$  and  $BV_2$  and

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the tissue portions located therebetween, surrounding the passageway 10, as shown in Figure 9c. The toroidal balloon member 620, 622 may be inflated with a gelatinous or curable polymeric substance which will fully or partially solidify after the toroidal balloon member 620, 622 have become inflated, thereby avoiding any problem with down-line leakage or deflation of the toroidal balloon member 620, 622.

Figure 9d shows a fourth embodiment of a longitudinal compression apparatus 22d which comprises an annular first magnet 626 and an annular second magnet 628 connected by a plurality of longitudinal connector members 630. The apparatus 22d is initially deployed within the passageway 10 such that the first annular magnet 626 is positioned adjacent the luminal surface of the first blood vessel  $BV_1$  and the second annular magnet 628 is positioned adjacent the luminal surface of the second blood vessel  $BV_2$ . These annular magnets 626, 628 are then allowed to magnetically move toward one another such that the longitudinal connector members 630 will become engaged and will longitudinally connect the magnets, thereby compressing the adjacent portions of the walls of blood vessels  $BV_1$ ,  $BV_2$  and any tissue positioned therebetween, which surrounds the passageway 10.

Figure 9e shows a fifth embodiment of a longitudinal compression apparatus 22e comprising a first ring member 632 and a second ring member 634, which may be compressed inwardly and connected by inflation of first and second balloons 640, 642. At least one connector member 636 extends from the inner side of the first ring member 632. At least one corresponding receiving aperture (not shown) is/are formed in the second ring member 634, and such receiving aperture(s) is/are sized and configured to receive the connector member(s) 636, and to engage ratchet serrations or other engagable surfaces formed on the connector member(s) 636. The apparatus 22e is mounted within the passageway 10 by initially advancing the



Figures 9f-9f'''' show a sixth embodiment of a longitudinal compression apparatus 22f which may be mounted within the extravascular passageway 10 formed between two blood vessels BV<sub>1</sub>, BV<sub>2</sub>, in accordance with the present invention. As shown, this apparatus 22f comprises a plurality of substantially parallel, elongate, pre-bent, resilient wire members 646 arranged in a generally cylindrical array. Optionally, a cylindrical connector member 648 formed of rigid or pliable material may be connected to each of the individual wire members 646 so as to hold them in the desired cylindrical array. Each wire member 646 is pre-bent so that, when unconstrained, the opposite ends of each wire member 646 will curl outwardly so as to cause the wire member to assume a generally "C" shaped configuration, as shown by the dotted lines in Figure 9f''. Initially, the apparatus 22f is mounted within the

lumen 652 of a tubular delivery catheter 650. An inner tubular catheter member 654 is positioned coaxially within the lumen 652 of the delivery catheter 650. The inner catheter 654 has a distal portion 656 of reduced outer diameter. The apparatus 22f is mounted within the lumen 652 of the delivery catheter 656 such that the individual wire members 646 are constrained and held in substantially straight configurations. The proximal ends of the wire members 646 are captured between the outer surface of the distal portion 656 of the inner tubular catheter 654 and the inner luminal wall of the outer catheter 650 as shown in Figure 9f'. The apparatus 22f is implanted within the passageway 10 by initially passing the delivery catheter 650 into the passageway 10 such that the distal end of the delivery catheter is flush with the luminal surface of the first blood vessel BV<sub>1</sub> as shown in Figure 9f'. Thereafter, the inner tubular catheter 654 is advanced in the distal direction to cause the distal ends of the wire members 646 to emerge out of the distal end of the outer catheter 650, thereby allowing the distal end of the wire member 646 to curl outwardly and abut or become compressively inserted within the luminal surface of the first blood vessel BV<sub>1</sub>, as shown in Figure 9f'''. Thereafter, the inner catheter 654 is retracted slightly in the proximal direction to release the proximal lens of the wire members 646 from frictional engagement and capture between the distal portion 656 of the inner tube 654 and the inner luminal surface of the outer tube 650. Thereafter, the entire catheter 650 is retracted in the proximal direction thereby liberating the entire apparatus 22f from the constraint of the surrounding catheter 650 and allowing the proximal ends of the wire members 646 to curl and to abut with or become compressively inserted into the luminal surface of the second blood vessel BV<sub>2</sub>, as shown in Figure 9f'''. In this manner, the apparatus, 22f serves to compress the walls of the blood vessels BV<sub>1</sub>,

BV<sub>2</sub>, and any tissue interposed therebetween, in the area surrounding the passageway 10. Additionally, as shown in Figure 9f''', it will be appreciated that in embodiments wherein the cylindrical connector member 648 is employed, such cylindrical connector member may comprise a segment of synthetic or bioprosthetic graft material so as to form a substantially tubular inner lining within the passageway 10, as illustrated in Figure 9f''''.

It will be appreciated that, although the apparatus 22f has been described hereabove as a pre-bent resilient structure, the wire members 646 may alternatively be formed of malleable metal or other pressure-deformable material and a suitable deformation tool such as an inflatable balloon may be deployed within the introducer catheter 650 so as to volitionally pressure-deform the ends of the wire members 646 as they pass out of the catheter tube 650, thereby providing the desired pre-bent "C" shaped configuration.

v. A Preferred Passageway-Forming Catheter and System

Figures 10a-11d show two basic embodiments of a preferred passageway-forming catheter, and accompanying apparatus which combine to form a passageway-forming system, in accordance with the present invention. Figures 12a-13b provide step-by-step showings of the preferred method for utilizing the passageway-forming catheters and system shown in Figures 10a-11d, to create an extravascular passageway 10 between two adjacent blood vessels BV<sub>1</sub>, BV<sub>2</sub>.

With reference to Figure 10a-10c, there is shown a first embodiment of a preferred passageway-forming catheter device 100p, which comprises an elongate, flexible catheter body 700 having a lumen 702 extending longitudinally therethrough and terminating, at its distal end, in a distal outlet aperture 704. A tissue-penetrating element 102, which may comprise any suitable tissue-penetrating element including any of those shown

in Figures 7a-7k and described hereabove, is disposed within the lumen 702 of the catheter body 700. It will be appreciated that the outlet aperture 704 and configuration of the lumen 702 may be modified to accommodate any of the suitable outlet schemes for passing the tissue-penetrating element out of the outlet aperture 704, including those penetrating-element outlet schemes shown specifically in Figures 6a-6i, and described hereabove.

The flexible catheter body 700 is preferably formed of a flexible polymer material such as nylon, pebax, polyethylene, etc., or pliable metal tubing such as a thin walled hypotubing. A metal braid or other reinforcement material may be mounted upon or formed within the wall of the catheter body 700 to provide structural reinforcement and to permit the catheter body 700 to be rotated or torqued without undue disfigurement or crimping. Additionally, in embodiments wherein the tissue-penetrating element 102 comprises a pre-bent, resilient member or needle, a rigid tubular reinforcement member 701 may be positioned about a distal portion of the lumen 702 of the catheter body 700, as shown in Figure 10b, to provide rigid constraint for the pre-bent distal portion of the penetrating element 102 when the penetrating element 102 is retracted into the lumen 702 of the catheter body 700. The presence of such tubular reinforcement member 701 will additionally prevent any sharpened distal tip on the tissue-penetrating element 102 from scarring or penetrating into the relatively soft plastic material of which the catheter body 700 may be made.

A hand piece 706 is mounted on the proximal end of the pliable catheter body 700. The handpiece 706 comprises a rigid outer shell having a generally cylindrical, hollow inner cavity 712 formed therewithin. A proximal portion of the tissue-penetrating element 102 extends into the inner cavity 712 of the handpiece 706.

An actuator button 710 is connected to the tissue-penetrating element 102, as shown in Figure 10c. The actuator button 710 may be depressed and advanced in the distal direction to cause the tissue-penetrating element  
5 102 to pass out of the outlet aperture 704 for the purpose of forming an extravascular passageway 10 of the present invention. Thereafter, the actuator button 710 may be retracted in the proximal direction to retract the tissue-penetrating element into the lumen 702 of the  
10 flexible catheter body 700.

Optionally, an imaging catheter side car 720 may be attached to the distal portion of the flexible catheter body 700. This imaging catheter side car 720 comprises an elongate tube having a lumen 722 extending  
15 longitudinally therethrough. A window 724 is formed in the upper side wall of the side car 720, immediately adjacent the outlet aperture 704. An imaging catheter 50, such as an intravascular ultrasound catheter of the types commercially available from Boston  
20 Scientific/Cardiovascular Imaging, MA; Endosonics, Inc., Pleasonton, CA; and Hewlett-Packard, North Andover, MA., is insertable into the lumen 722 of the side car 720 such that the sensor portion 52 (e.g., portion where the imaging ultrasound is emitted and received) is positioned  
25 next to window 724. The material of which the side car 720 is made is preferably a material which will prevent transmission of the type of energy (e.g., ultrasound) which is utilized by the imaging catheter 50, but the window 724 is either an open aperture is covered with a  
30 material which may be permeated by the energy utilized by the imaging catheter 50. In this manner, the sensor portion 52 of the imaging catheter 50 will receive an image only of the area which is in alignment with the window 724. Additionally, the window 724 is preferably  
35 of a rectangular configuration and is confined to the side wall of the side car 720 which is immediately adjacent the outlet aperture 704 of the flexible catheter

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body 700. In this manner, such specific sizing, configuration and positioning of the window 724 may permit the user to accomplish precise rotational orientation of the catheter apparatus 100p by simply  
5 rotating the apparatus 100p until the target tissue (e.g., other blood vessel) is clearly viewed by the imaging catheter 50 through the window 724, thereby indicating that the outlet aperture 704 is positioned correctly so that subsequent passage of the tissue-  
10 penetrating element 102 out of the outlet aperture 704 will cause the tissue-penetrating element 102 to advance through the wall of the blood vessel in which the catheter apparatus 100p is located, and into the target tissue (e.g., other blood vessel). Moreover, such  
15 positioning of the window 724 will permit the imaging catheter 50 to be utilized to observe the actual movement and penetration of the tissue-penetrating member 102, thereby ensuring that the extravascular passageway is formed at the desired location.

20 As an alternative to formation of a window 724 at a discrete location within the side car 720, the distal end of the side car 720 may be located adjacent the site at which the tissue penetrating member 102 passes out of the catheter body 700 and the sensor portion 52 of the  
25 imaging catheter 50 may simply extend out of and beyond the distal end of the side car 720 such that it may clearly image the deployment and movement of the tissue-penetrating element 102. In this alternative arrangement the field imaged by the imaging catheter 50 will no  
30 longer be limited or inhibited by the window 724 and the imaging catheter 50 may be capable of imaging in a full 360° radius about the distal end of the side car 720. Accordingly, any suitable types of marker apparatus or marking materials may be formed on the catheter apparatus  
35 100p or tissue-penetrating element 102p to permit the imaging catheter 550 to be utilized for the desired function of determining the correct rotational

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orientation of the catheter device 100p prior to deployment or actuation of the tissue penetrating element 102.

5 Additionally, as described hereabove, a guide wire lumen 726 may extend longitudinally through the tissue-penetrating element 102 and may terminate distally in a guide wire outlet aperture 728 formed in the distal end of the tissue-penetrating element 102. In this manner, a guide wire GW may extend through the tissue-penetrating  
10 element 102 and may be advanced out of guide wire outlet aperture 728.

In embodiments wherein the tissue-penetrating element 102 is provided with a guide wire lumen 726 and guide wire outlet aperture 728 at its distal end, the  
15 presence of a guide wire GW within such lumen 726 may be utilized as a means for accurately determining when the distal end of the tissue-penetrating element 102 has penetrated into the lumen of a target blood vessel or other cavity or open area. To accomplish this, continual  
20 or intermittent distally-directed pressure will be applied to the guide wire GW as the tissue-penetrating element 102 is advanced through the wall of the blood vessel in which the catheter apparatus 100p is located and through any other extravascular tissue through which  
25 the passageway 10 is to pass. So long as the distal end of the tissue-penetrating element 102 is in abutment with tissue, the guide wire GW will be prevented from emerging and advancing out of the distal end guide wire outlet aperture 728 and, accordingly, the distally directed  
30 pressure applied to the guide wire GW will be met with resistance due to the presence of the tissue abutting against the guide wire outlet aperture 728. However, when the distal end of the tissue-penetrating element 102 enters into the lumen of the target blood vessel or other  
35 open space, the guide wire outlet aperture 728 will immediately become uncovered and the guide wire GW will be permitted to rapidly advance out of the guide wire

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outlet aperture 728 in response to the distally directed pressure being applied thereto. Such rapid advancement of the guide wire GW will signal to the operator that the distal tip of the tissue-penetrating element 102 has, in fact, entered the lumen of the target blood vessel or other open space. At that point, advancement of the tissue-penetrating element 102 may be volitionally stopped, so as to avoid any possibility that the tissue-penetrating element will perforate the contralateral wall of the target blood vessel or other tissue on the other side of open area within which the passageway 10 is to extend.

Figure 10c'-10c''' provide a schematic illustration of an apparatus which may be incorporated into the passageway-forming catheter 100p to exert continuous or intermittent distally directed pressure on the guide wire GW, as described hereabove, for determining when the distal end of the tissue-penetrating element 102 has passed into the lumen of the target blood vessel or other open space. With reference to Figures 10c'-10c''', the apparatus 800 comprises one or more springs 802 which are connected, by way of a connector member 804 to a portion of the guide wire GW which protrudes out of the proximal end of the catheter body 700. It will be appreciated that the apparatus 800 may be incorporated within the inner cavity 712 of the handpiece 706, or may be formed as a separate unit which is mountable upon the proximal end of the handpiece 706.

As shown in Figure 10c, prior to commencement of the procedure, the guide wire GW may freely extend out of the outlet aperture 728 in the distal end of the tissue-penetrating element 102, thereby allowing the spring members 802 of the apparatus 800 to assume a relaxed (e.g., shortened) configuration.

Figure 10c'' shows that, when the tissue-penetrating element 102 is being advanced through tissue, the distal end of the guide wire GW will be maintained flush with



the outlet aperture 728, and the spring members 802 of the apparatus 800 will become stressed (e.g., elongated) due to the distally-directed pressure being applied by the distal tip of the guide wire GW against the adjacent  
5 tissue.

Figure 10c''' shows that, when the distal tip of the tissue penetrating element 102 has emerged into the lumen of a blood vessel or other open area, the guide wire GW will immediately advance out of the guide wire outlet  
10 aperture 728, thereby allowing the spring members 802 of the apparatus 800 to once again assume their relaxed (e.g., shortened) configuration. This abrupt advancement of the guide wire and relaxation of the spring members 802 will signal to the operator, that the tissue-  
15 penetrating element 102 has arrived within the lumen of the blood vessel or other open space, and that further advancement of the tissue-penetrating element 102 should be ceased.

As stated hereabove it shall be appreciated and  
20 understood that the pressure-exerting apparatus described and shown in Figures 10c''-10c''' is optional need not necessarily be included within the catheter device 100p. Moreover, it shall be understood and appreciated that continuous or intermittent urging of the guide wire GW in  
25 the distal direction may be accomplished manually (i.e., by hand) without the need for the use of any apparatus.

Figures 11a-11d show the manner in which the preferred passageway-forming catheter and system 100p may be modified to accommodate the specific type of tissue-  
30 penetrating element 102f shown in Figure 7f and described hereabove. This particular tissue penetrating element is made up of an inner puncturing member 322 and a longitudinally advanceable outer sheath 326.

Figures 11a-11d show a modified preferred catheter  
35 device 100p' which, like the above-described embodiment of the catheter device 100p, comprises a flexible catheter body 700 having a lumen 702 extending

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mechanical or temporal relationship to one another to accomplish the novel methods described herein, and may be used in any one of the numerous combinations possible that sufficiently accomplish the stated objectives. Such  
5 systems may include a catheter body dimensioned to fit within a blood vessel and advanceable to a location which is in proximity to an extravascular target or neighboring vascular target. The catheter can further be combined in some way with one or more of the described active or  
10 passive orientation means to assist in the proper positioning of the catheter in the blood vessel with respect to the target. Further, the catheter may incorporate at least one of the tissue-penetrating elements such that a passageway may be formed from the  
15 blood vessel to the target. The system may also incorporate a guide wire dimensioned to be inserted into the passageway, and introducible through the catheter such that it may enter the passageway and provide a rail to the target. The system may also incorporate the  
20 placement of one or more of the devices that are positionable or insertable into the passageway over the guide wire, such as channel sizing and maintenance means or other devices for accomplishing a therapeutic or diagnostic end-point. Also, the systems may include one  
25 or more of the various blood vessel blocking means such that a blood vessel in operative association with an extravascular passageway of the present invention may be blocked or occluded to allow the re-routing of blood.

30 **vi. Operation of the Preferred Embodiments of the  
Passageway-Forming Catheter and System**

Figures 12a-12d provide a step-by-step showing of the preferred method of using the first embodiment of the tissue-penetrating catheter device and system 100p shown in Figures 10-10c'''.  
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Figures 13a-13b provide a step-by-step showing of the preferred method of using the second embodiment of

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the preferred passageway-forming catheter device and system 100p'.

With reference to Figure 12a-12d, an imaging catheter 50 is inserted into the lumen 722 of the side car 720 such that the imaging sensor portion 52 of the catheter 50 is positioned adjacent window 724. In this manner, the combination of the imaging catheter 50 with the passageway-forming catheter device 100' forms a "system" in accordance with the present invention. With the tissue-penetrating element 102 retracted into the lumen 704 of the flexible catheter body 700 such that the distal tip of the tissue-penetrating element 102 is housed within tubular reinforcement member 701, the system comprising the catheter apparatus 100p and imaging catheter 50 is inserted into the vasculature of a mammalian patient and advanced until the distal end of the catheter body 700 and distal end of the side car 720 are positioned within a first blood vessel  $BV_1$  located adjacent a second blood vessel  $BV_2$  with the invention of forming a passageway 10 between the first blood vessel  $BV_1$  and second blood vessel  $BV_2$ .

The catheter device 100p is then rotated until the imaging field IF viewed by the imaging catheter 50 through the window 724 clearly views the second blood vessel  $BV_2$  into which the passageway 10 is to extend. This indicates that the catheter device 100t has been placed in the correct rotational orientation to allow the tissue-penetrating element 102 to form the passageway 10 at the desired location, such that it will extend into the second blood vessel  $BV_2$ . Thereafter, the actuator button 710 will be advanced until the distal tip of the tissue-penetrating element 102 begins to penetrate through the wall of the first blood vessel  $BV_1$ . Optionally, intermittent or continuous distally directed pressure may be applied to the guide wire GW by hand (i.e., manually) or by a pressure-exerting apparatus 800,

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as advancement of the tissue-penetrating element 102 continues.

With reference to Figure 12b, as soon as the distal tip of the tissue-penetrating element 102 emerges into the lumen of the second blood vessel  $BV_2$ , the guide wire GW will promptly advance in the distal direction, thereby signaling to the operator that the advancement of the tissue-penetrating member 702 should be ceased. At that point, the operator will discontinue further advancement of the actuator button 710.

Thereafter, the actuator button 710 will be retracted to its full proximal point so as to retract the tissue-penetrating element 102 into the lumen 702 of the catheter body 700, while allowing the guide wire GW to remain extended through the newly-formed passageway 10 and into the lumen of the second blood vessel  $BV_2$ .

As show in Figure 12c, the passageway-forming catheter device 100p and accompanying imaging catheter 50 may then be extracted and removed from the body, leaving the guide wire GW positioned through the first blood vessel  $BV_1$ , through the passageway 10 and into the second blood vessel  $BV_2$ .

As shown in Figure 12d, a passageway modifying apparatus 500, such as any of the types of passageway modifying apparatus 500 shown in Figure 8a-8h, may then be advanced over the guide wire GB to modify (e.g., enlarge, debulk, treat, coat, etc.) the passageway 10.

It will be appreciated that, after the step shown in Figure 12v has been completed, the guide wire GW may be left in place through the passageway 10 to allow any desired stents, stented grafts, or passageway constraining apparatus 22 as shown in Figures 9a-9f to be deployed within the passageway 10.

Figures 13a-13e illustrate a step-by-step preferred method for utilizing the modified embodiment of the passageway-forming catheter device and system 100p shown in Figures 11a-11b.

Initially, the desired imaging catheter 50 is inserted into the lumen 722 of the side car 720 such that the imaging catheter 50 and passageway-forming catheter device 100p' will, in combination, a passageway-forming "system".

The passageway-forming catheter 100p and accompanying imaging catheter 50 are then advanced into the vasculature to a point where the distal ends of the catheter body 700 and side car 720 are positioned within a first blood vessel  $BV_1$  immediately adjacent a second blood vessel  $BV_2$ , between which a passageway 10 is to be formed. The imaging catheter 50 is then energized such that the sensor portion 52 of the imaging catheter will receive an image within the image field IF through window 724. The catheter device 100p' is then rotated until the second blood vessel  $BV_2$  into which the passageway 10 is to extend is clearly imaged by the imaging catheter 50 through window 724. This indicates that the correct rotational orientation and position of the catheter device 100p' has been attained. Additionally, the catheter device 100p' may be longitudinally moved until the desired flow characteristics are observed within the second blood vessel  $BV_2$  in the image field IF, thereby indicating that the catheter device 100p is in its correct longitudinal position. Additionally, the imaging catheter 50 may be utilized to determine the distance between the first blood vessel  $BV_1$  and second blood vessel  $BV_2$ , so as to define the distance which the tissue-penetrating element 102f should be deployed to form the desired passageway 10 from the first blood vessel  $BV_1$  to the second blood vessel  $BV_2$ .

As shown in Figure 13a, after the catheter 100p' has been longitudinally and rotationally orientated, the tissue-penetrating element 102f is deployed out of the catheter body 700, and begins to advance through the wall of the first blood vessel  $BV_1$ . The outer sheath 326 of the tissue penetrating element 102f will be in a slightly

retracted position such that the trocar tip 324 extends out of the distal end of the sheath 326 to accomplish the desired penetration through tissue.

During the advancement of the tissue-penetrating element 102f as shown in Figure 13a, manual pressure or pressure exerted by apparatus 800 may be utilized to apply distally directed pressure to the sheath 326. In this manner, when the trocar tip 324 of the tissue-penetrating element 102f enters the lumen of the second blood vessel BV<sub>2</sub>, the sheath 326 will immediately advance forwardly into the lumen of the second blood vessel BV<sub>2</sub>, thereby signaling to the operator that the desired passageway 10 has been formed and that any further advancement of the tissue-penetrating element 102f should be ceased.

Figure 13b shows that, after the sheath 326 has advanced into the lumen of the second blood vessel BV<sub>2</sub>, the elongate trocar tipped member 322 may be extracted and removed, thereby leaving the sheath 326 as a conduit through the passageway 10.

As shown in Figure 13c, a guide wire GW may then be passed through the lumen of the sheath 326 and into the second blood vessel BV<sub>2</sub>.

Thereafter, as shown in Figure 13d, passageway-  
25 forming catheter device 100p' and accompanying imaging  
catheter 50 may be extracted and removed from the body,  
thereby leaving the guide wire GW in place, and extending  
through the lumen of the first blood vessel BV<sub>1</sub>, through  
the passageway 10 and into the second blood vessel BV<sub>2</sub>.

30           Thereafter, as shown in Figure 13e, any suitable type of passageway-modifying apparatus 500 may be advanced over the pre-positioned guide wire GW to effect the desired modification of the passageway 10.

It will be appreciated that the invention has been  
35 described hereabove with reference to certain specific  
embodiments and examples only. No effort has been made  
to exhaustively describe all possible embodiments of the





**WHAT IS CLAIMED IS:**

1. A method for revascularization, said method comprising the step of:

5 a) forming an extravascular passageway between a first location on a blood vessel and a second location on a blood vessel, such that blood having a  $pO_2$  of at least 50 will flow through said extravascular passageway.

10 2. The method of Claim 1 wherein said first location and said second location are on at least one blood vessel of the heart.

3. The method of Claim 1 wherein said first location and said second location are on the same blood vessel.

15 4. The method of Claim 1 wherein said first location and said second location are on different blood vessels.

5. The method of Claim 4 wherein said blood vessels are a artery and a vein.

20 6. The method of Claim 4 wherein said blood vessels are a vein and a vein.

7. The method of Claim 4 wherein said blood vessels are an artery and an artery.

25 8. The method of Claim 4 wherein a plurality of said extravascular passageways are formed between said blood vessels.

9. The method of Claim 1 wherein said extravascular passageway is formed for the purpose of bypassing an obstructed, injured or diseased segment of  
30 a blood vessel.

10. The method of Claim 1 wherein said first location is on an artery and said second location is on a vein, such that blood will flow from said artery, through said extravascular passageway, and into said  
35 vein.

11. The method of Claim 10 wherein blood which has entered the vein through said extravascular passageway is

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subsequently caused to flow through said vein so as to retroperfuse tissue through the venous vasculature.

12. The method of Claim 11 wherein said blood is caused to flow through the vein so as to retroperfuse  
5 tissue through venous vasculature by:

b) blocking said vein at a location adjacent said extravascular passageway to cause blood which flows into said vein through said extravascular passageway to subsequently flow through said vein in  
10 a direction which will cause said retroperfusion of tissue through the venous vasculature.

13. The method of Claim 1 wherein the extravascular passageway formed in step a is a primary extravascular passageway formed between a first blood vessel and a  
15 second blood vessel such that blood having a  $pO_2$  of at least 50 will flow from the first blood vessel, through said extravascular passageway, and into the second blood vessel.

14. The method of Claim 13 wherein said method  
20 further comprises the step of:

b) forming at least one secondary extravascular passageway between said second blood vessel and another blood vessel of the heart such that blood which has entered the second blood vessel  
25 through the first extravascular passageway will subsequently flow into another blood vessel through said secondary extravascular passageway.

15. The method of Claim 14 wherein said blood is caused to flow into the other blood vessel through the  
30 secondary extravascular passageway by:

c) blocking the second blood vessel at a location adjacent the second extravascular passageway to cause said blood to flow from said second blood vessel through said second  
35 extravascular passageway and back into said other blood vessel.

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5 is present. 17. The method of Claim 1 wherein step a  
of said method is carried out by:

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23. The method of Claim 22 wherein said arterial blood is caused to flow through the vein so as to retroperfuse cardiac tissue through the cardiac venous vasculature by blocking flow through the vein in an opposite direction, at a location adjacent an  
5 extravascular passageway.

24. The method of Claim 21 wherein the method further comprises:

utilizing said catheter to form at least one  
10 secondary extravascular passageway from said vein of the heart to an artery of the heart such that arterial blood which has entered said vein of the heart will subsequently flow through said at least one secondary extravascular passageway and into an  
15 artery of the heart, so as to profuse cardiac tissues through the cardiac arterial vasculature.

25. The method of Claim 20 wherein said method is carried out for the purpose of bypassing an obstructed, injured or disease-affected segment of an artery of the  
20 heart.

26. The method of Claim 25 wherein said revascularization is performed in the heart of a mammal having a Circumflex Artery, a Great Cardiac Vein, an Anterior Interventricular Vein and a Left Anterior  
25 Descending Artery for the purpose of bypassing an obstructed, injured or disease-affected segment of the Circumflex Artery, wherein said method further comprises:

i. forming a primary extravascular passageway between the Left Anterior Descending Artery and the  
30 Anterior Interventricular Vein;

ii. forming a secondary extravascular passageway between the Great Cardiac Vein and the Circumflex Artery at a location downstream of the obstructed, injured or disease-affected segment  
35 thereof; and,

iii. causing blood to flow from the Left Anterior Descending Artery through the primary

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extravascular passageway, through the Anterior Interventricular Vein into the Great Cardiac Vein, and through the secondary extravascular passageway into the Circumflex Artery, downstream of the obstructed, injured or disease-affected segment thereof.

27. The method of Claim 26 wherein step iii is accomplished by blocking the lumen of the Anterior Interventricular Vein at a location adjacent the primary extravascular passageway.

28. The method of Claim 27 wherein step iii is further accomplished by blocking the lumen of the Great Cardiac Vein at a location adjacent the secondary extravascular passageway.

29. The method of Claim 25 wherein said revascularization is performed in the heart of a mammal having a Circumflex Artery, a Great Cardiac Vein, an Anterior Interventricular Vein, and a Left Anterior Descending Artery for the purpose of bypassing an obstructed, injured or disease-affected segment of the Left Anterior Descending Artery, wherein said method further comprises:

i. forming a primary extravascular passageway between the Circumflex Artery and the Great Cardiac Vein;

ii. forming a secondary extravascular passageway between the Anterior Interventricular Vein and the Left Anterior Descending Artery at a location downstream of the obstructed, injured or diseased-affected segment thereof; and,

iii. causing blood to flow from the Circumflex Artery, through the primary extravascular passageway, through the Great Cardiac Vein into the Anterior Interventricular Vein, and through the secondary extravascular passageway into the Left Anterior Descending Artery downstream of the

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obstructed, injured or disease-affected segment thereof.

30. The method of Claim 29 wherein step iii is accomplished by blocking the lumen of the Great Cardiac Vein at a location adjacent the primary extravascular passageway.

31. The method of Claim 30 wherein step iii is further accomplished by blocking the lumen of the Anterior Interventricular Vein at a location adjacent the secondary extravascular passageway.

32. A method for performing a medical procedure at an intracorporeal target location within a mammalian body, said method comprising the steps of:

a) positioning, within a blood vessel a catheter device which comprises:

i) a flexible catheter body having a proximal end and a distal end;

ii) a tissue-penetrating element passable out of a first location on said catheter body to form an extravascular passageway which extends from the blood vessel in which the catheter is positioned to an intracorporeal target location outside of said blood vessel;

b) orienting the first location of the catheter body relative to the intracorporeal target location such that the tissue-penetrating element may pass out of the first location of the catheter body to form an extravascular passageway between said blood vessel and said intracorporeal target location;

c) passing the tissue-penetrating element out of the catheter body to form said extravascular passageway between said blood vessel and said intracorporeal target location; and,

d) passing at least one procedure-performing apparatus through said extravascular passageway and

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utilizing said procedure-performing apparatus to perform said medical procedure at said intracorporeal target location.

33. The method of Claim 32 wherein said medical  
5 procedure is the delivery of a flowable substance, and wherein said procedure-performing apparatus comprises a tubular cannula through which said flowable substance may be passed into said extravascular location.

34. The method of Claim 32 wherein said medical  
10 procedure is the implantation of an implantable drug delivery apparatus, and wherein said procedure-performing apparatus is an implantation device for passing said drug delivery apparatus through said extravascular passageway and for implanting said delivery apparatus at said  
15 extravascular location.

35. The method of Claim 32 wherein said medical  
procedure is the implantation of radioactive matter for radiotherapy, and wherein said procedure-performing  
20 apparatus is an implantation apparatus operative to pass said radioactive matter through said extravascular passageway and to implant said radioactive matter at said extravascular location.

36. The method of Claim 32 wherein said medical  
procedure is the implantation of a stimulator apparatus  
25 and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said stimulator apparatus through said extravascular passageway and for implanting said stimulator apparatus at said  
extravascular location.

37. The method of Claim 32 wherein said medical  
30 procedure is the implantation of a sensor apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said sensor apparatus through said extravascular passageway and for implanting  
35 said sensor apparatus at said extravascular location.

38. The method of Claim 32 wherein said medical  
procedure is the implantation of a electrode apparatus

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deployed to an operative configuration to impart structural support to at least one anatomical structure located at said extravascular location.

44. The method of Claim 32 wherein said medical  
5 procedure is the implantation of a marker apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said marker apparatus through said extravascular passageway and for implanting said marker apparatus at said extravascular location.

10 45. The method of Claim 44 wherein said marker is formed of radiographically visible material.

46. The method of Claim 32 wherein said medical procedure is tissue ablation, and wherein said procedure-performing apparatus is a tissue ablating apparatus.

15 47. The method of Claim 32 wherein said medical procedure is tissue destruction, and wherein said procedure-performing apparatus is a tissue destruction apparatus.

20 48. The method of Claim 32 wherein said medical procedure is tissue cutting, and wherein said procedure-performing apparatus is a tissue cutting apparatus.

49. The method of Claim 48 wherein the medical procedure is transection of a nerve, and wherein said procedure-performing apparatus is a nerve-transecting  
25 apparatus.

50. The method of Claim 32 wherein the medical procedure is the sampling of a biological fluid, and wherein said procedure-performing apparatus is a cannula through which a sample of biological fluid may be  
30 aspirated from said extravascular location.

51. The method of Claim 32 wherein the medical procedure is a sampling of solid matter, and wherein said procedure-performing apparatus is an apparatus for removing a sample of solid matter from said extravascular  
35 location.

52. The method of Claim 51 wherein said medical procedure is a tissue biopsy, and wherein said procedure-

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53. The method of Claim 32 wherein said method  
5 further comprises:

54. The method of Claim 32 further comprising:  
positioning a tubular cannula within said  
10 extravascular passageway and causing said tubular  
cannula to remain indwelling within said  
extravascular passageway following extraction and  
removal of said catheter.

56. The method of Claim 54 wherein said indwelling tubular cannula is accessible from any extracorporeal location to permit desired matter to be delivered through said cannula to said extravascular location.

58. The method of Claim 53 wherein said method  
30 further comprises:

59. The method of Claim 58 wherein the closing of  
35 said opening in the blood vessel is carried out by the  
deployment of a blood vessel wall closing apparatus  
selected from the group of apparatus consisting of:

an energy-emitting device;  
a cautery device;  
a suturing device;  
a stapling device;  
5 an endovascular graft;  
a stented endovascular graft;  
a balloon;  
a coil;  
strands of coagulation producing materials;  
10 microfibrillar collagen;  
collagen sponge;  
cellulose gel; and,  
combinations thereof.

60. A catheter device insertable into a blood  
15 vessel and useable to form an extravascular passageway  
which extends through the wall of the blood vessel in  
which the catheter device is inserted, to an  
intracorporeal target location, said catheter device  
comprising:

20 a flexible catheter body having a proximal end  
and distal end;

a tissue-penetrating element passable out of a  
first location on the catheter body to form said  
extravascular passageway; and,

25 orientation means for determining at least the  
rotational orientation of the catheter body to  
facilitate proper positioning of the first location  
on the catheter body such that subsequent passage of  
the tissue-penetrating element from the catheter  
30 body will form said extravascular passageway between  
said blood vessel and said intracorporeal target  
location.

61. The device of Claim 60 wherein said first  
location is an outlet aperture formed in the distal end  
35 of said catheter body and said tissue penetrating element  
is passable out of said outlet aperture, and wherein said  
tissue-penetrating element is adapted to bend in a first

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direction as it passes out of said outlet aperture formed in the distal end of said catheter body, to thereby penetrate the wall of the blood vessel in which the catheter has been inserted.

5           62. The device of Claim 60 wherein said first location is an outlet aperture formed in the side wall of the catheter body, and wherein said tissue-penetrating element, when passed out of said outlet aperture located in the side wall of said catheter body will penetrate  
10 through the wall of the blood vessel into which the catheter has been inserted.

          63. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate, pliable needle having a sharp distal tip and a pre-bent resilient spine  
15 member positioned therewithin, said spine member being operative to cause said pliable needle to bend in said first direction.

          64. The device of Claim 60 wherein said tissue-penetrating element is an elongate member which  
20 comprises:

- i) a pliable proximal shaft having a distal end, and
- ii) a sharpened tip member formed of rigid material and mounted on the distal end of said  
25 pliable proximal shaft.

          65. The device of Claim 60 wherein said tissue-penetrating element comprises a resilient, pre-bent member having a sharpened distal tip.

          66. The device of Claim 65 wherein said needle is  
30 formed of a material which is superelastic when inserted within the mammalian body.

          67. The device of Claim 66 wherein said super elastic material is a nickel-titanium alloy.

          68. The device of Claim 66 wherein said pre-bent  
35 resilient member is a hollow needle having a hollow lumen extending longitudinally therethrough.

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69. The device of Claim 66 wherein said pre-bent resilient member is a solid needle.

70. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having  
5 a trocar tip formed on the distal end thereof, in combination with a tubular sheath disposed around said needle member and longitudinally moveable relative to said needle member.

71. The device of Claim 60 wherein said tissue-  
10 penetrating element comprises an elongate member having an energy-emitting distal tip formed thereon, said energy-emitting distal tip being operative to emit energy which will facilitate penetration of said tissue-penetrating element through tissue.

72. The device of Claim 60 wherein the energy-emitting distal tip on said tissue-penetrating element is selected from the group of energy-emitting apparatus  
15 consisting of:

20 a resistance-heated tip;  
a monopolar electrocautery tip;  
a bipolar electrocautery tip;  
an ultrasound-emitting tip member; and,  
possible combinations thereof.

73. The device of Claim 60 wherein said tissue-  
25 penetrating element comprises an elongate member having a distal end with a rotating tissue-severing apparatus formed thereon.

74. The device of Claim 60 wherein said tissue-penetrating element is a flow of energy passable out of  
30 said outlet opening formed in said catheter body.

75. The device of Claim 60 wherein said flow of energy is selected from the group of energy types consisting of;

35 laser light;  
heat;  
ultrasound; and,  
possible combinations thereof.

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76. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having a lumen extending longitudinally therethrough, said lumen being connectable to a source of negative pressure so as to draw tissue into said lumen through the distal end of said tissue-penetrating element.

77. The device of Claim 60 wherein said tissue-penetrating element comprises:

a pre-bent resilient, tubular sheath having an open distal end; and,

an elongate member having a sharpened distal tip, said elongate member being disposed within said tubular sheath and advanceable therethrough, such that the sharpened distal tip will emerge out of the open distal end of the sheath;

said elongate member being constructed of material which is sufficiently pliable to conform to the pre-bent configuration of the tubular sheath.

78. The device of Claim 60 further comprising:

a side car apparatus connected to at least a distal portion of the flexible catheter body, said side car apparatus being configured to received therewithin an imaging catheter such that the imaging catheter may be utilized to observe passage of the tissue-penetrating element out of the first location on the catheter body.

79. The device of Claim 78 wherein said side car is formed of a material which is at least partially impermeable to the energy utilized by the imaging device, and wherein said side car further comprises:

a window formed in said side car immediately adjacent said first location on the catheter body to permit said imaging device to observe the passage of said tissue-penetrating element out of said first location on the catheter body and through the wall of the blood vessel in which the catheter is positioned.

80. The device of Claim 79 wherein said window is positioned in alignment with the direction in which said tissue-penetrating element will pass during creation of said extravascular passageway;

5           said window thereby comprising at least a portion of said orientation means, the orientation of the first location on said catheter body being thereby controllable by rotating the catheter device until an imaging apparatus positioned within the  
10           side car is able to view the target area into which the passageway is to be formed, thereby ensuring that the catheter device is in proper rotational orientation prior to advancement of the tissue-penetrating element out of the outlet aperture.

15           81. The device of Claim 60 wherein the catheter body is formed of a flexible plastic material, and wherein a rigid tubular reinforcement member is disposed about a portion of the lumen of said catheter body, adjacent the outlet aperture, to prevent the tissue-penetrating element from resting in contact with the  
20           pliable plastic material of the catheter body when the tissue-penetrating element is retracted into the catheter body.

25           82. The device of Claim 60 further comprising: a handpiece mounted on the proximal end of said catheter body, said handpiece having an actuator button which is connected to said tissue-penetrating element, said actuator button being advanceable in a first direction to advance said tissue-penetrating  
30           element out of said outlet aperture, and retractable in a second direction to retract said tissue-penetrating element into the lumen of said catheter body.

35           83. A system comprising the passageway-forming catheter device of Claim 60 further in combination with: an imaging apparatus which is usable in conjunction with said orientation means to further

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84. The system of Claim 83 wherein said imaging apparatus is selected from the group of imaging apparatus  
5 consisting of:

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85. The system of Claim 84 wherein said apparatus is an imaging catheter.

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said imaging catheter being positioned at least partially within said side car apparatus.

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said imaging catheter being located within said side car adjacent said window so as to limit the

field observed by said imaging catheter to that which is observable through said window.

86. The system of Claim 85 wherein said passageway-forming catheter device is torqueable such that said catheter device may be volitionally rotated until the imaging catheter is able to view the target area through said window, thereby ensuring that the first location on the catheter body is in the correct rotational position prior to passage of the tissue-penetrating element out of the first location on said catheter body.

87. The system comprising the catheter device of Claim 58 wherein the tissue-penetrating element comprises an elongate member having guide wire lumen extending longitudinally therethrough such that a guide wire may be advanced through said lumen upon formation of said extravascular passageway by said tissue-penetrating element, said system comprising:

said catheter device of Claim 58 further in combination with an elongate flexible guide wire which is passable through said guide wire lumen of said tissue-penetrating element.

88. A longitudinal compression apparatus useable to longitudinally compress tissue surrounding openings formed in first and second tubular anatomical conduits having lumens, wherein said first and second tubular anatomical conduits are in side-to-side juxtaposition to one another such that said openings are in alignment with one another, said longitudinal compression apparatus comprising:

a first portion positionable in abutment with the luminal surface of the first tubular anatomical conduit surrounding the opening therein;

a second portion positionable in abutment with the luminal surface of the second tubular anatomical conduit surrounding the opening formed therein;

means for connecting said first and second portions to each other, so as to longitudinally

compress the tissue which surrounds the aligned openings of the first and second anatomical conduits and any extravascular tissue interposed therebetween.

5        89. The longitudinal compression apparatus of Claim 88 wherein said first and second portions comprise annular members positionable in abutment with said luminal surfaces.

10       90. The longitudinal compression apparatus of Claim 88 wherein first and second portions comprise opposite ends of elongate wire members formed in a cylindrical array and extending through said first and second openings, said opposite ends of said wire members being outwardly bent so as to abut against and engage the  
15       luminal surfaces of said first and second anatomical conduits.

20       91. The longitudinal compression apparatus of Claim 90 wherein said wire members are pre-bent resilient wire members which, when positioned within said first and second openings and relieved of external constraint, will assume said bent configuration.

25       92. The longitudinal compression apparatus of Claim 90 wherein said wire members are plastically deformable, and wherein said device further comprises a pressure-exerting tool which is operative to bend the opposite ends of said wire members after said wire members have been positioned within said first and second openings.

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Abstract

Methods, devices, and systems for a) revascularization and/or b) performing other medical procedures at vascular or non-vascular intracorporeal locations within a mammalian body. The methods generally comprise the formation of at least one extravascular passageway from a blood vessel to a vascular or non-vascular target location. In the revascularization methods the extravascular passageway is utilized for blood flow. In the medical procedure methods the extravascular passageway is utilized as a conduit for accessing or performing procedures at the vascular or non-vascular target location. Also disclosed are catheter devices and systems which are useable to form the extravascular passageways of the invention, as well as apparatus for modifying, maintaining and/or closing such extravascular passageways.

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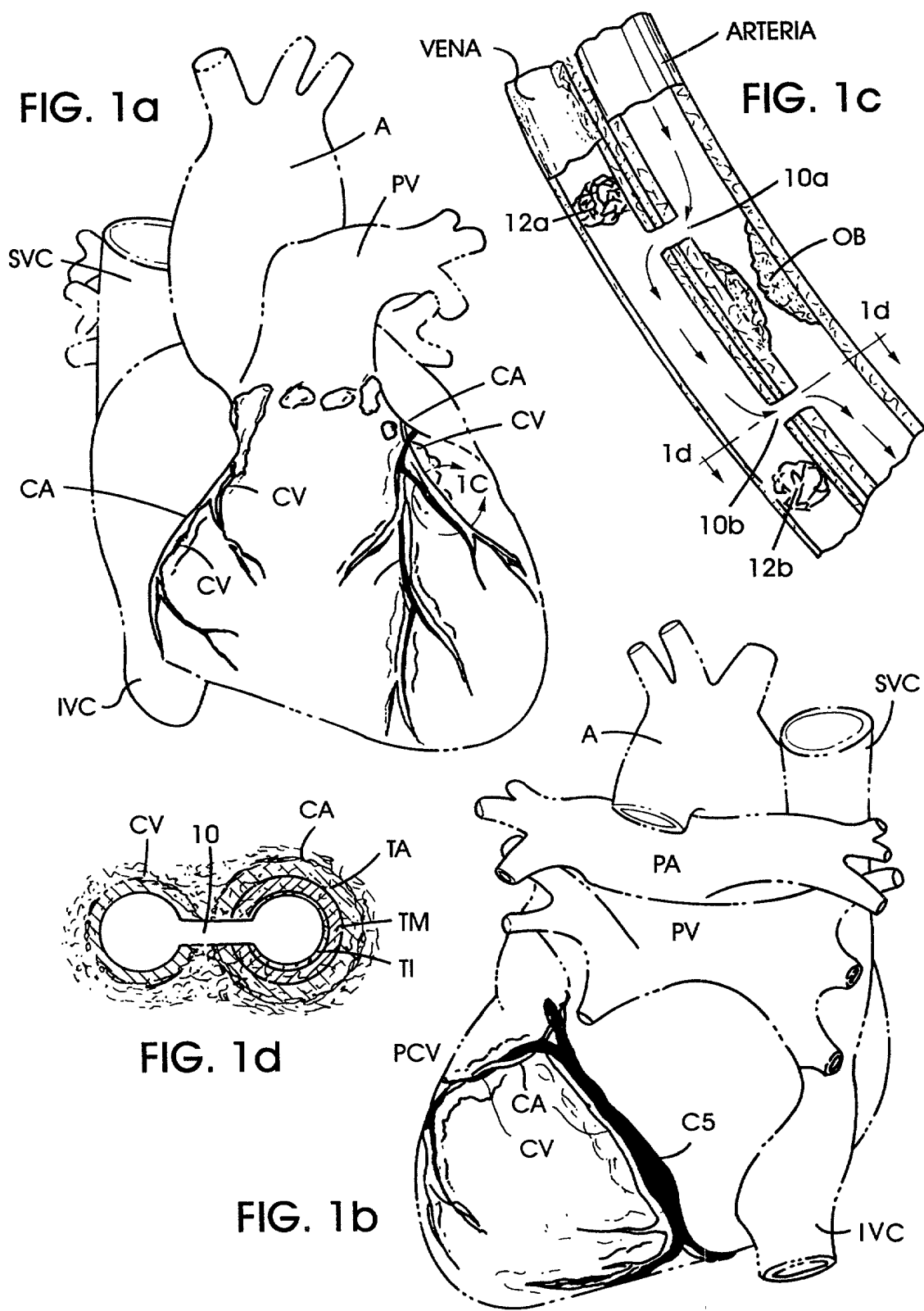


FIG. 1a

**FIG. 1c**

FIG. 1d

FIG. 1b

FIG. 1e

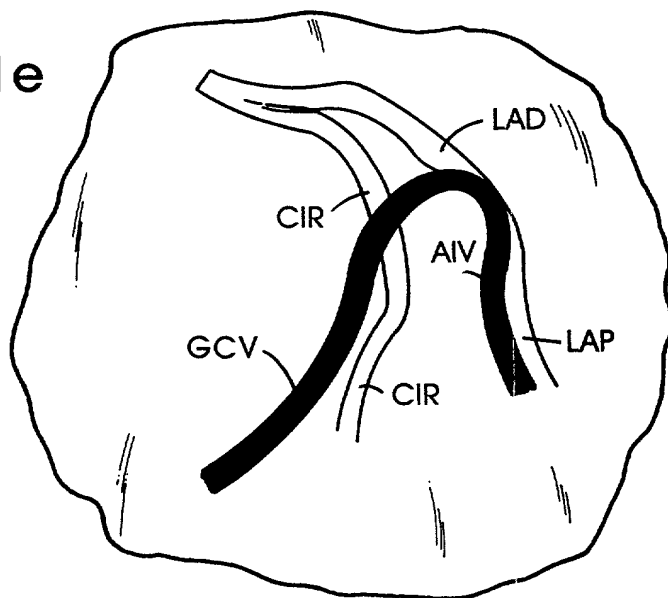


FIG. 1f

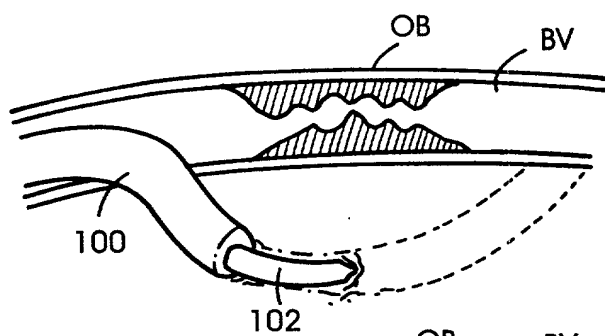
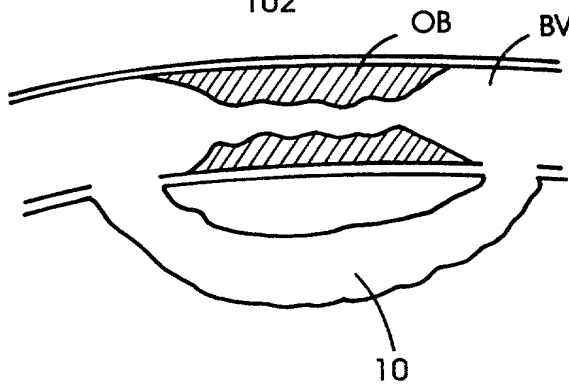


FIG. 1f'





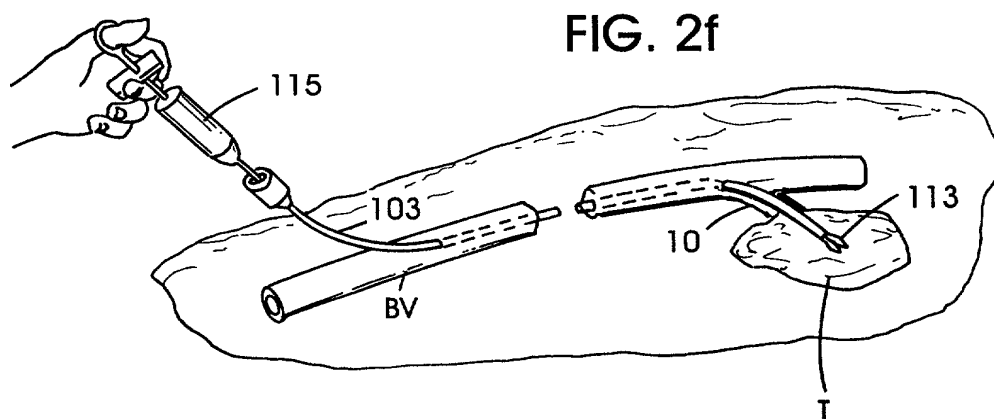
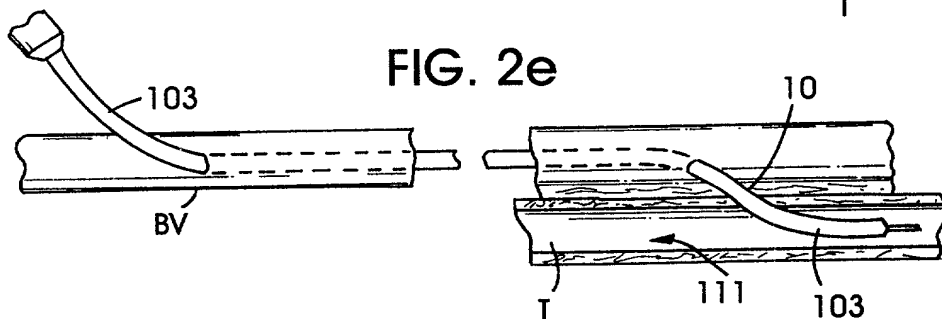
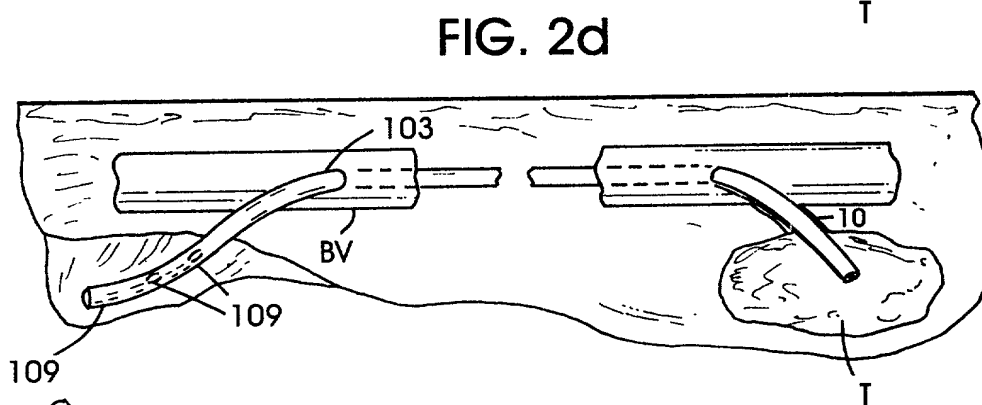
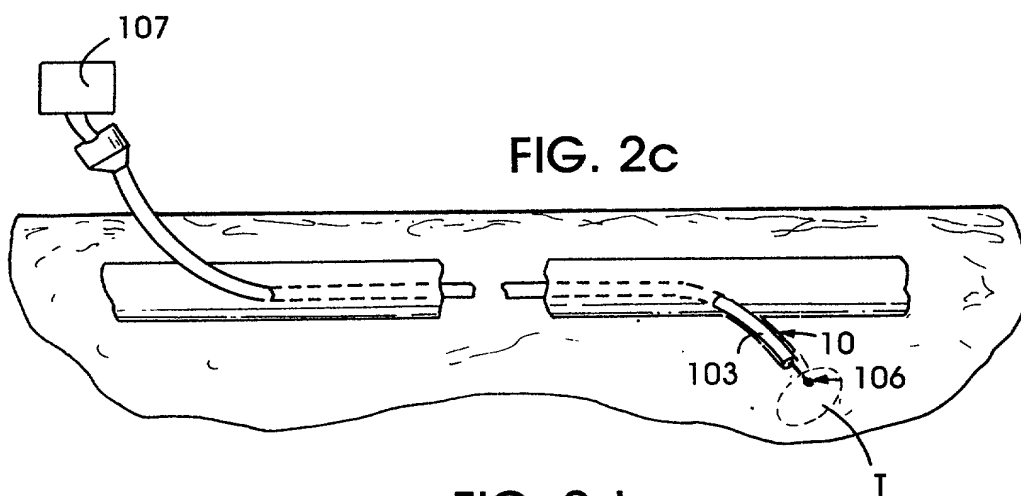




FIG. 3a

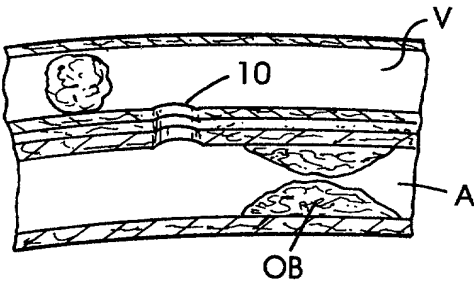


FIG. 3d

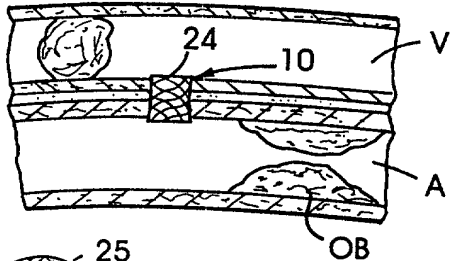


FIG. 3b

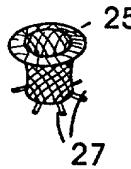
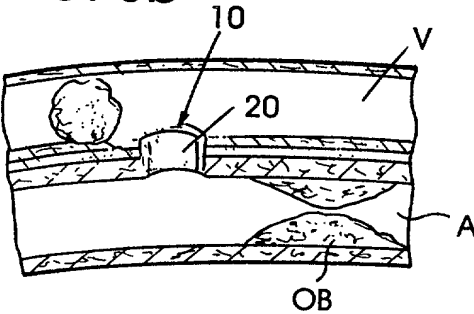


FIG. 3d'

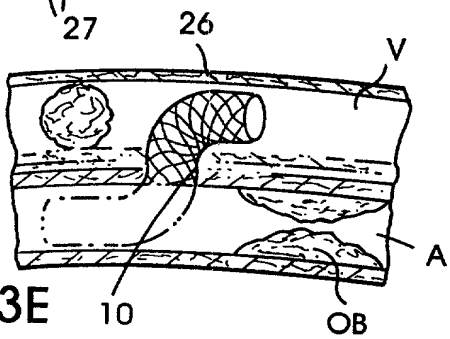


FIG. 3E

FIG. 3c

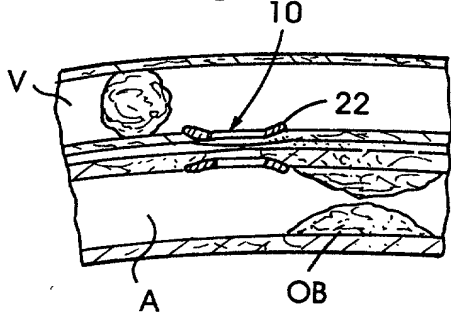


FIG. 3f

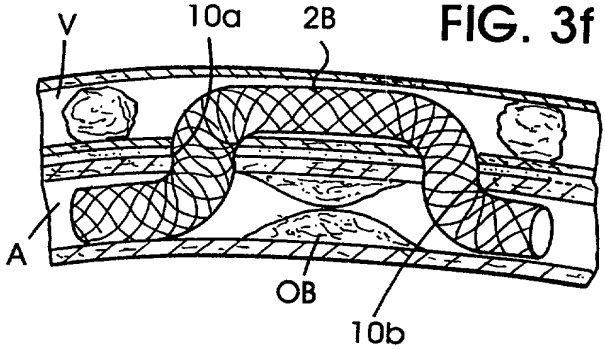


FIG. 4a

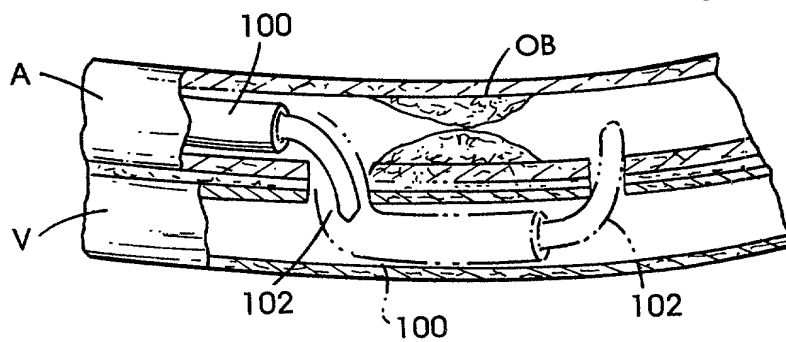


FIG. 4b

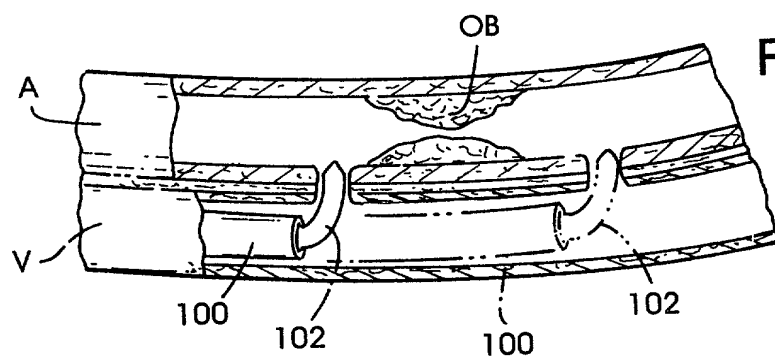


FIG. 4c

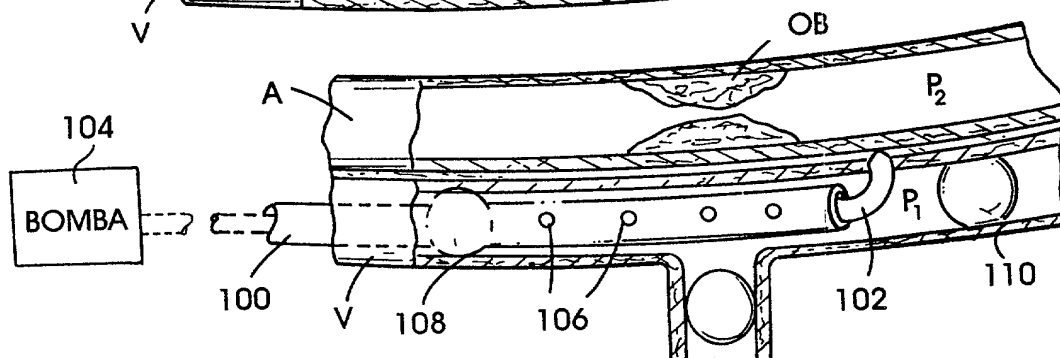
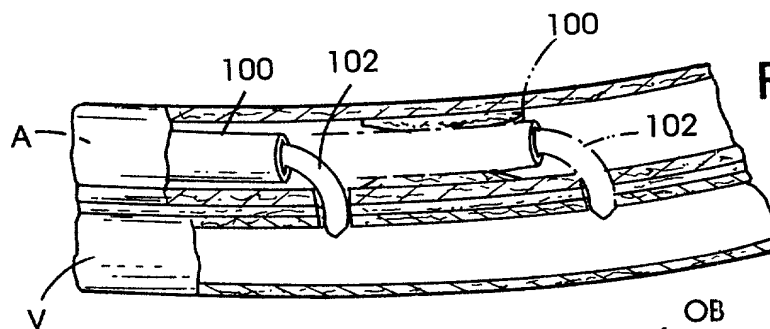
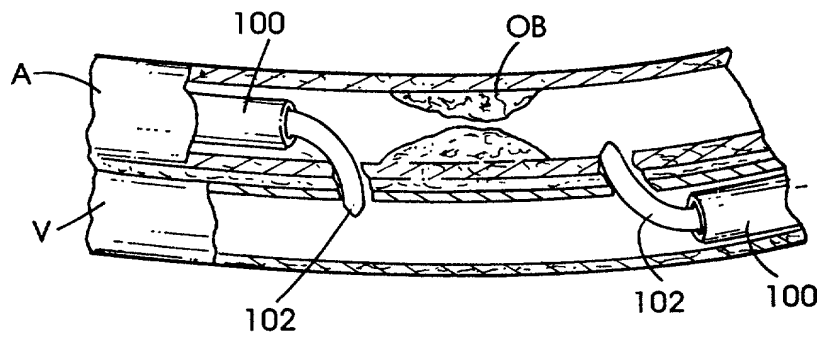


FIG. 4d

FIG. 4e



**FIG. 5a**

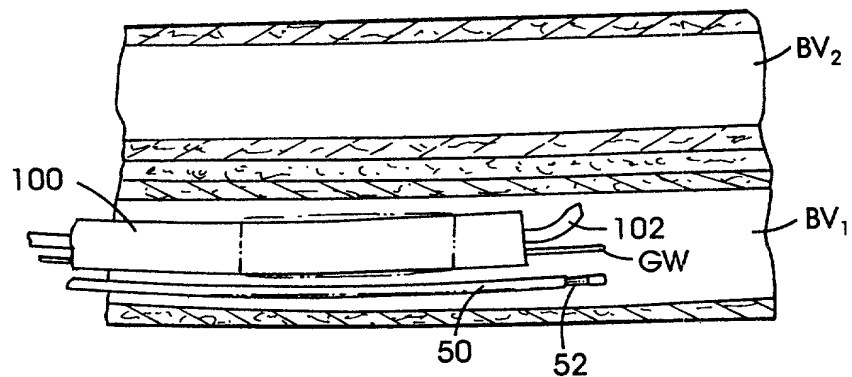
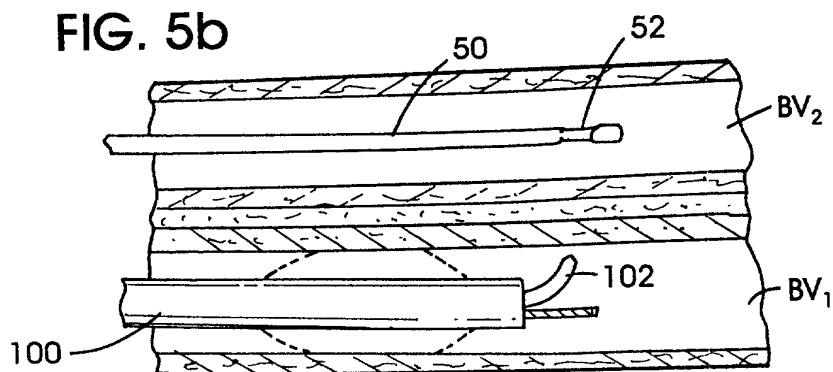


FIG. 5b



**FIG. 5c**

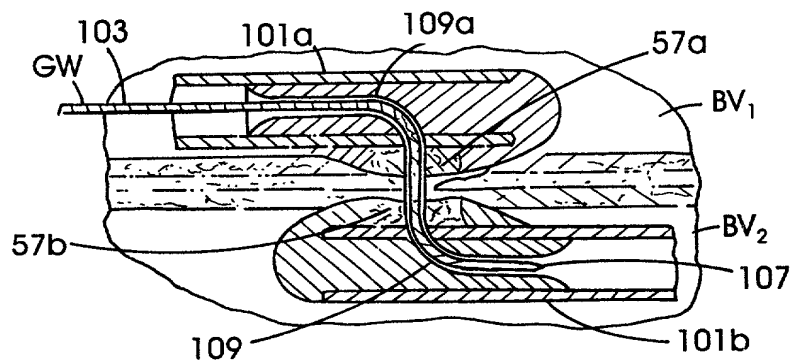
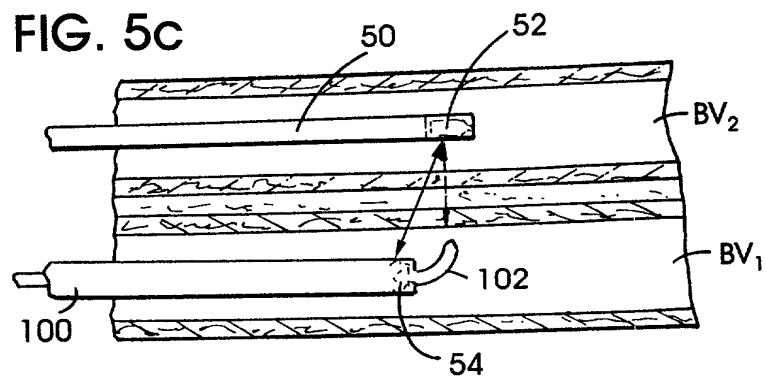


FIG. 5d

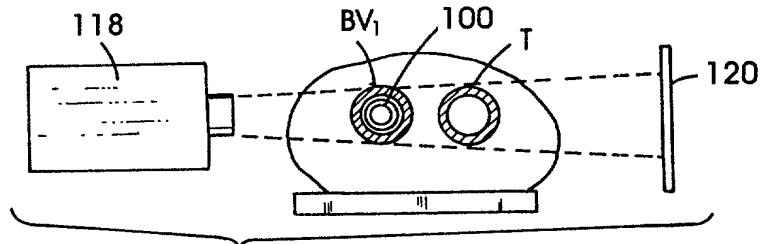


FIG. 5e

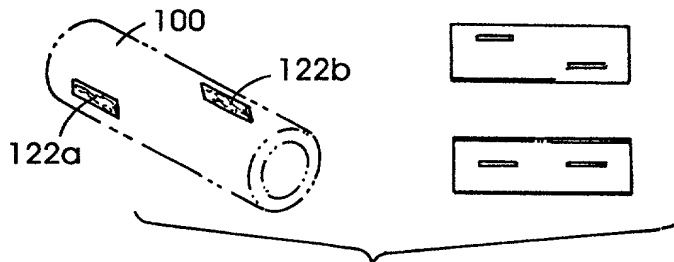


FIG. 5e'

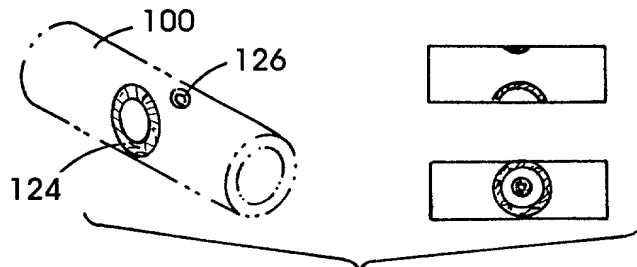


FIG. 5e''

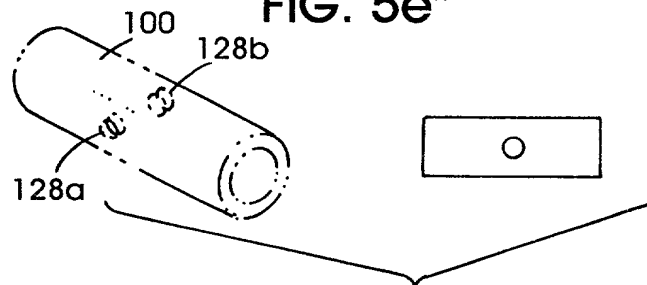


FIG. 5e'''

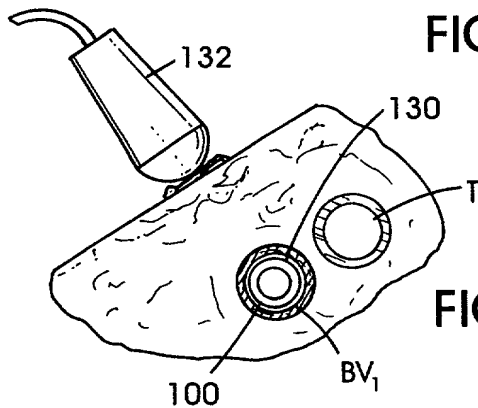


FIG. 5f

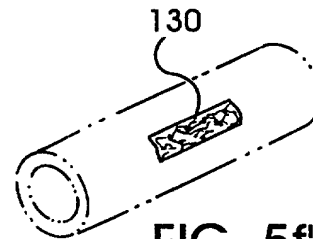


FIG. 5f'

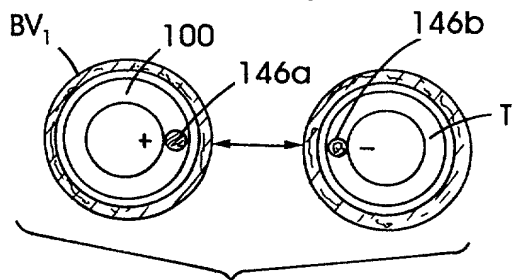
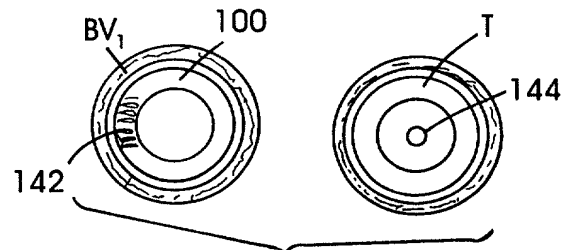
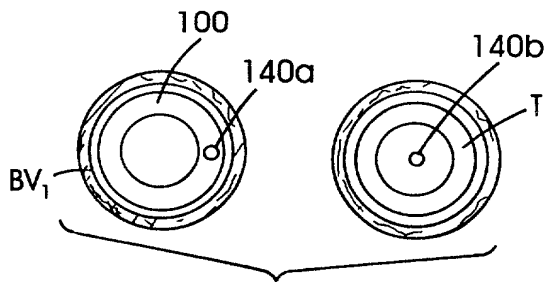
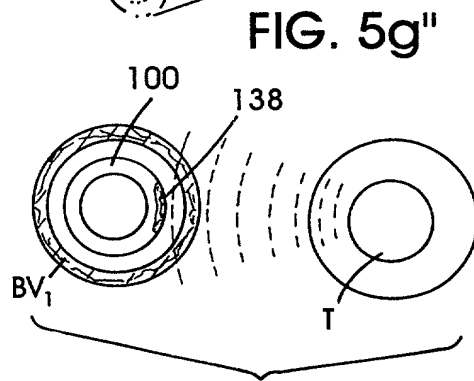
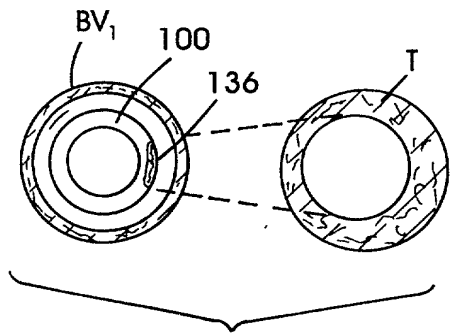
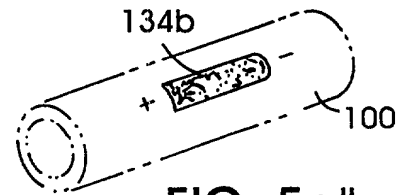
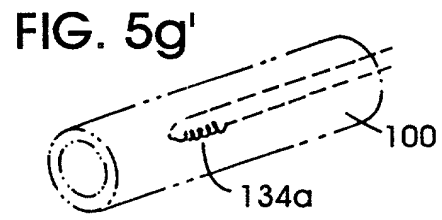
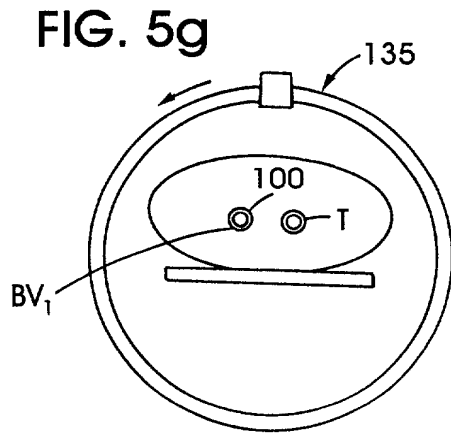




FIG. 6f

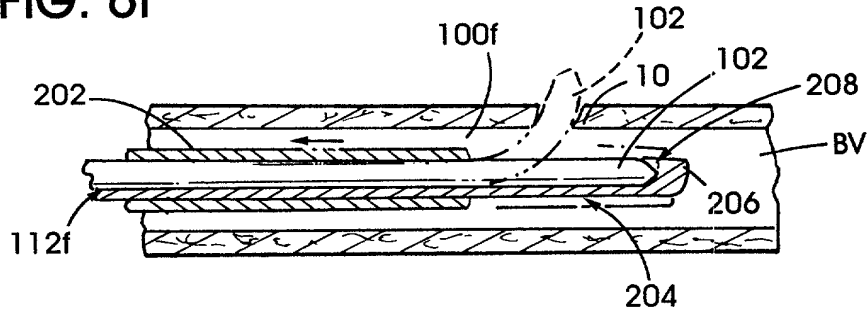


FIG. 6g

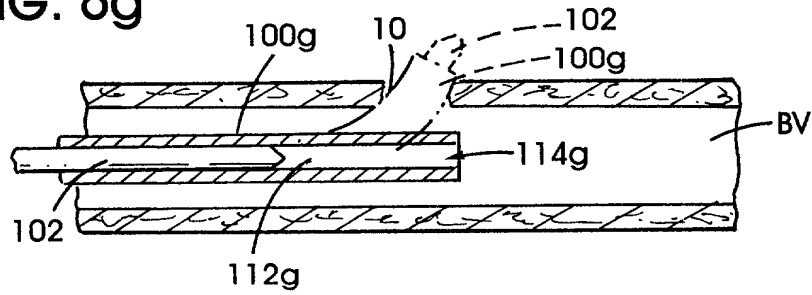


FIG. 6h

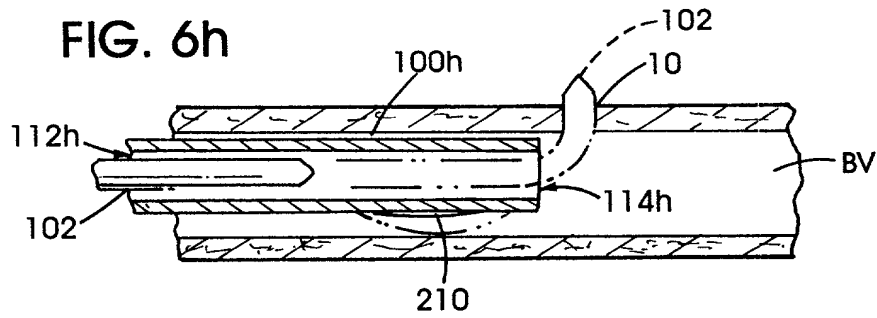
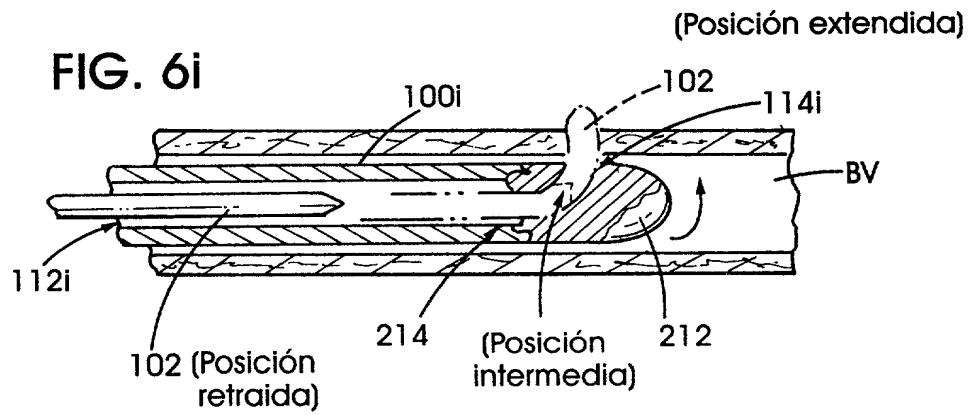
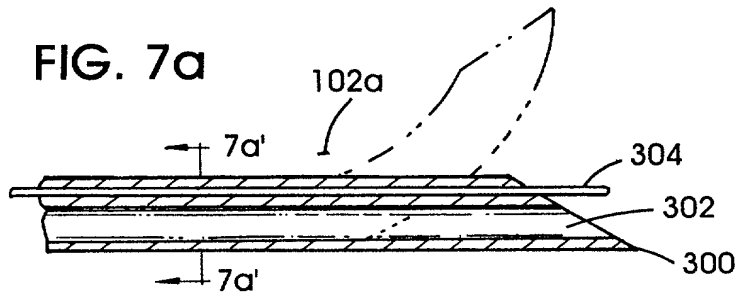


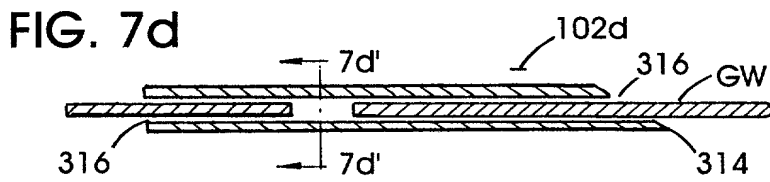
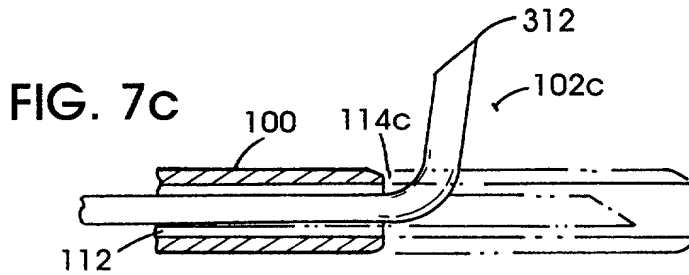
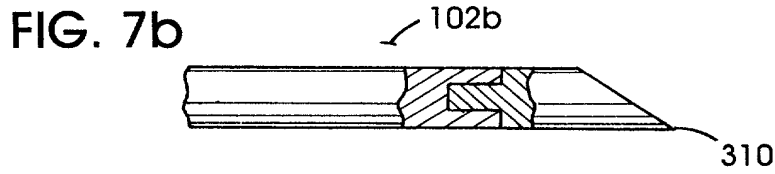
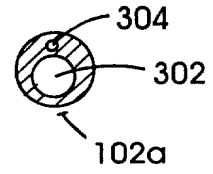
FIG. 6i



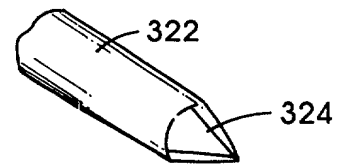
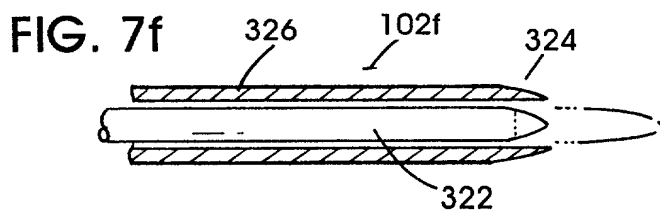
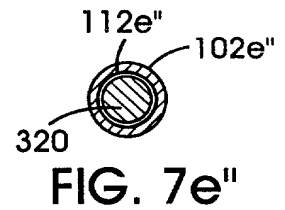
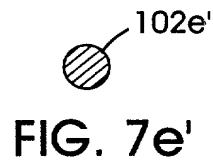
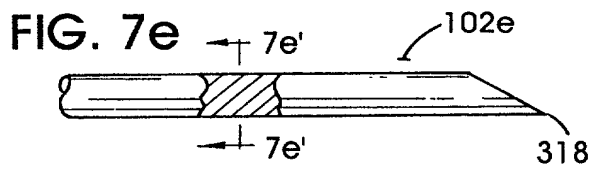




**FIG. 7a'**



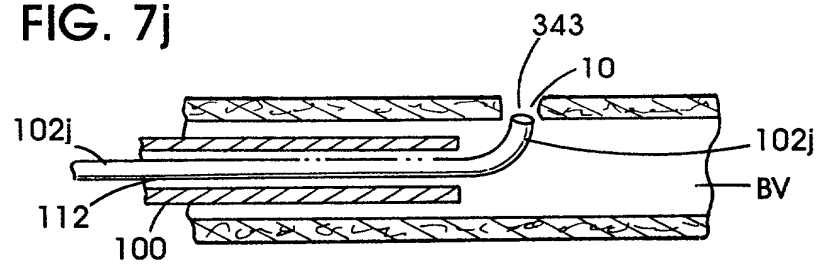
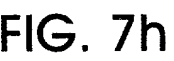
**FIG. 7d'**



**FIG. 7f'**

**FIG. 7g**

FIG. 7g is a cross-sectional view of a device 100. The device has a tapered tip 330. A layer 102g is shown on the top surface. A feature 112 is located on the left side. A dashed line 332 indicates a boundary or interface. Concentric dashed arcs on the right represent a field or wave emanating from the tip 330.



**FIG. 7k**

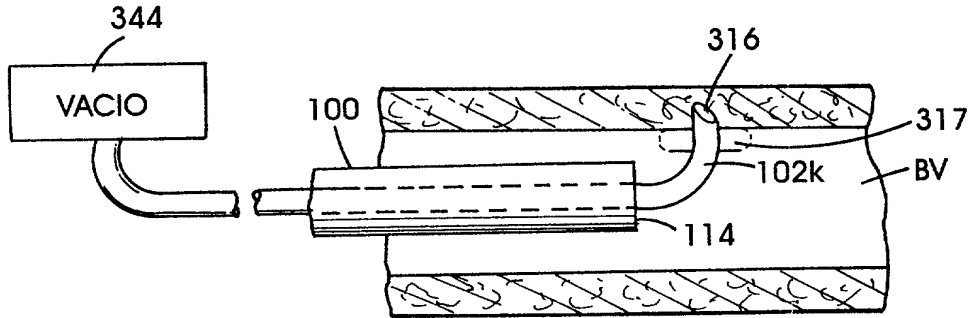
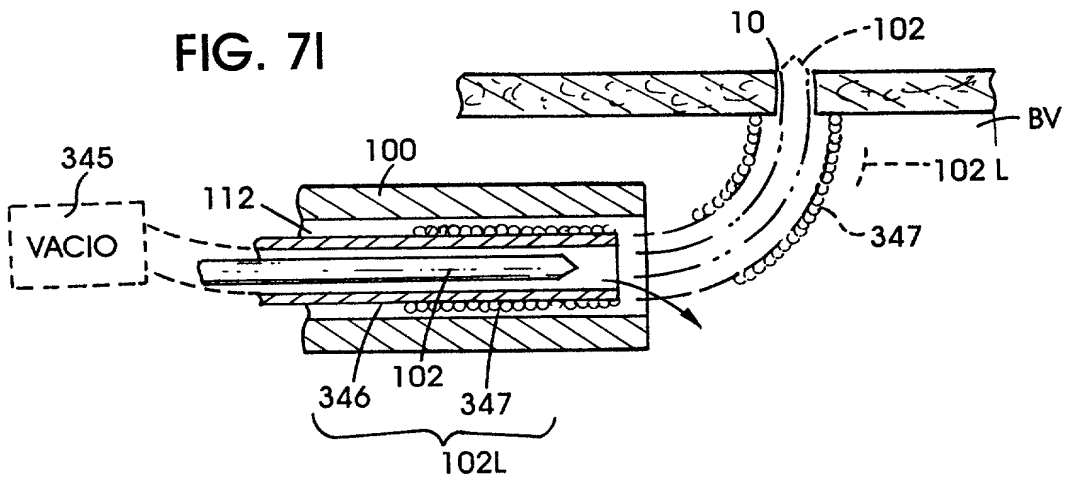


FIG. 71



**FIG. 7m**

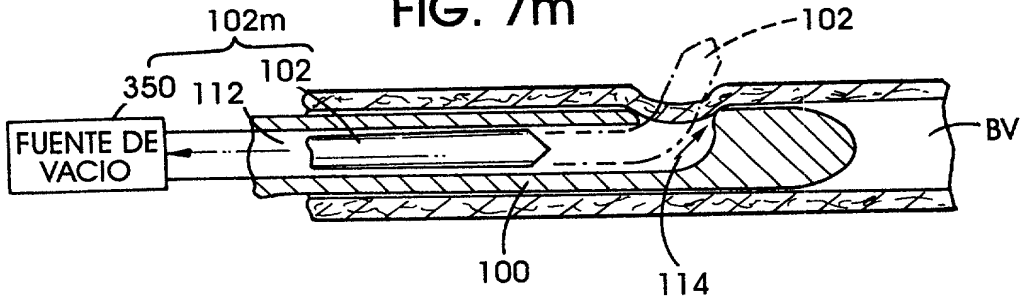


FIG. 8a

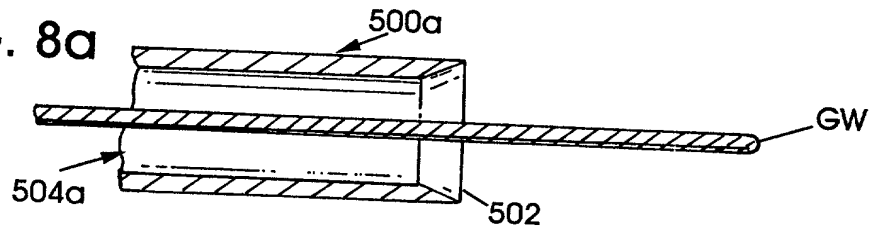


FIG. 8b

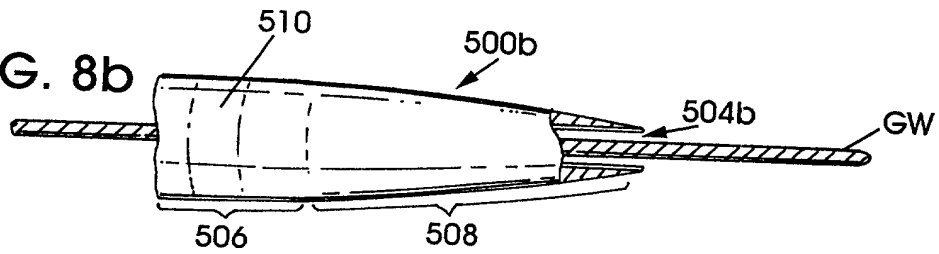


FIG. 8c

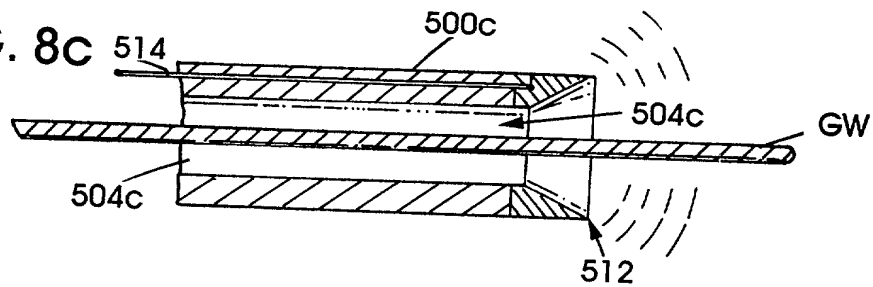


FIG. 8d

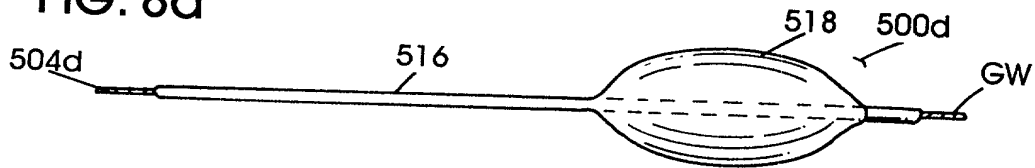
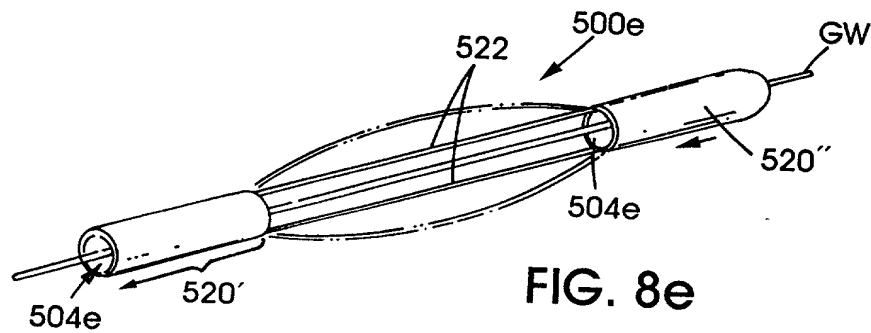


FIG. 8e



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FIG. 8f

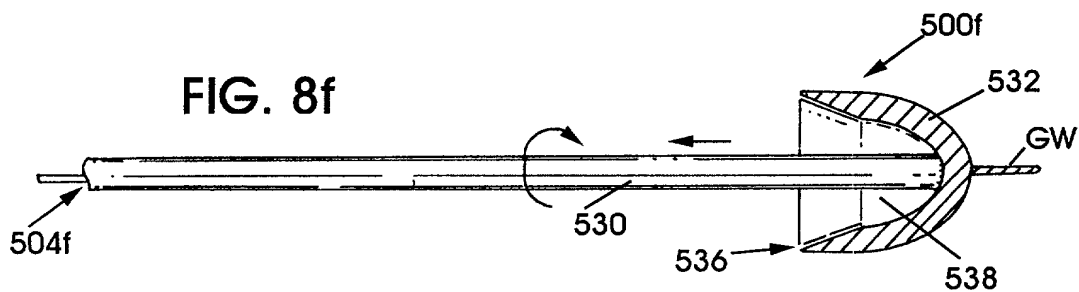


FIG. 8g

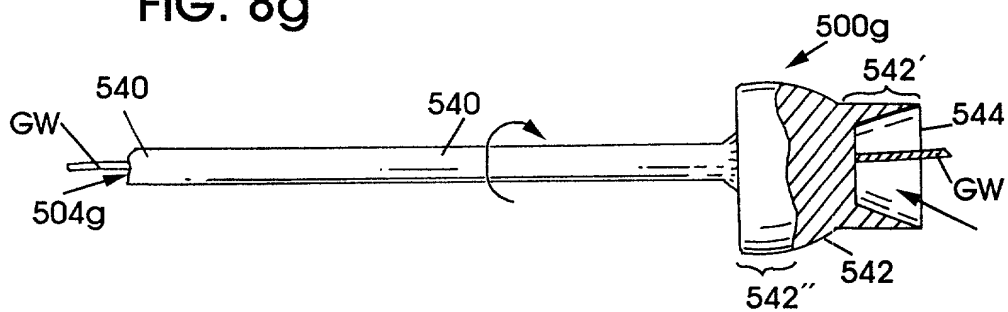


FIG. 8h

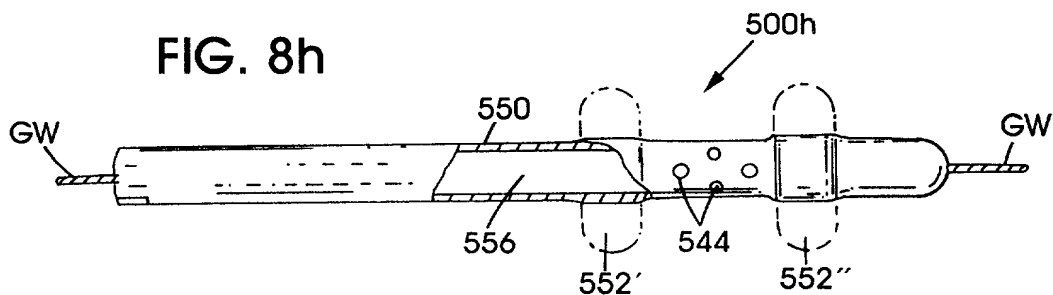


FIG. 8h''

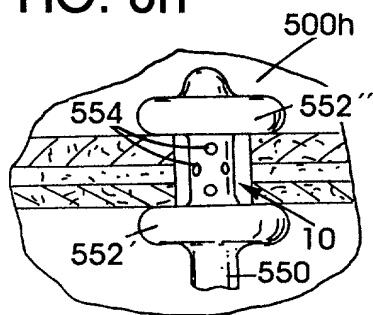
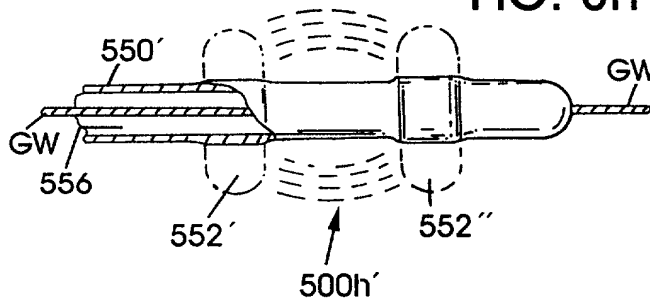


FIG. 8h'





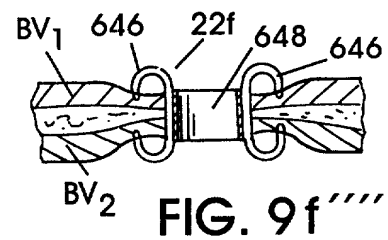
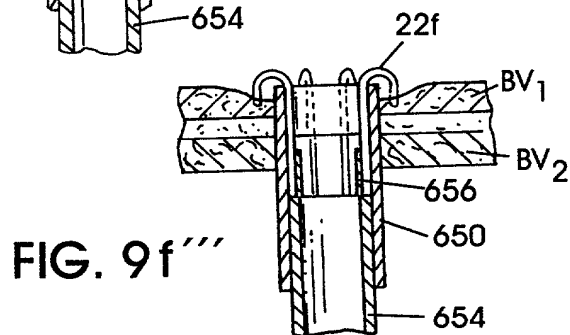
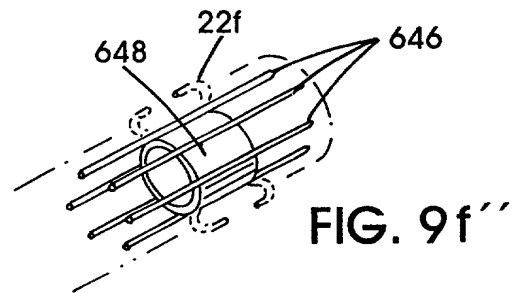
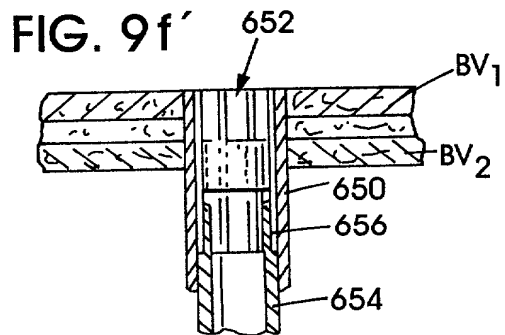
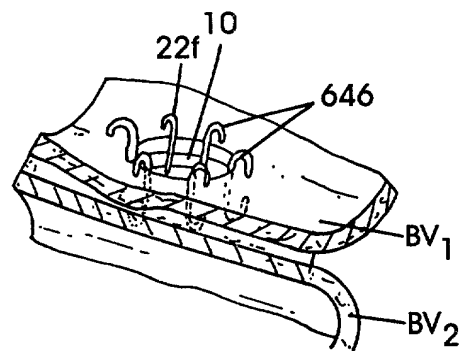
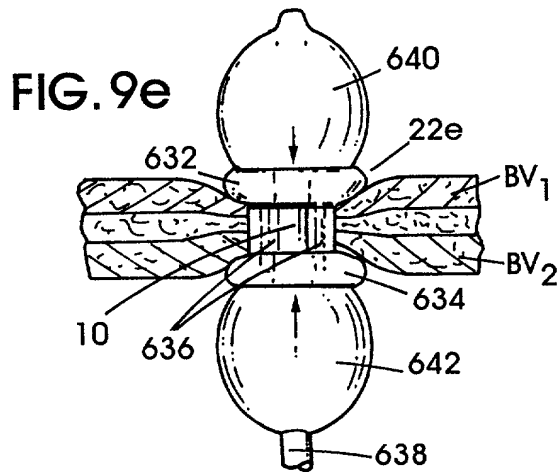
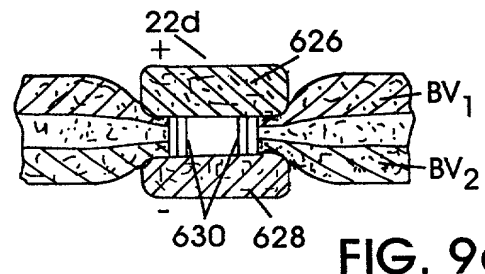
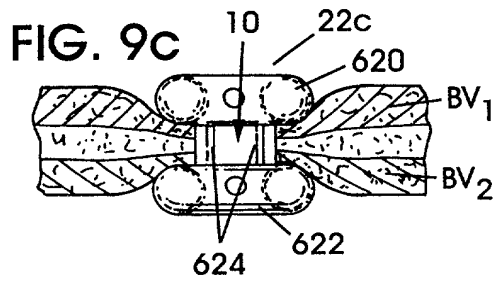






FIG. 11a

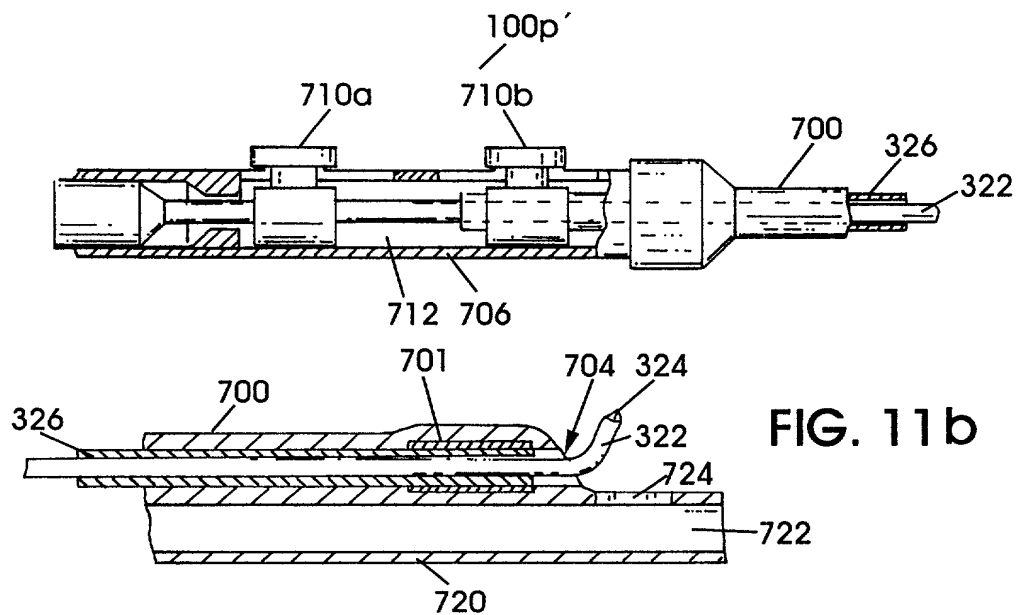


FIG. 11b

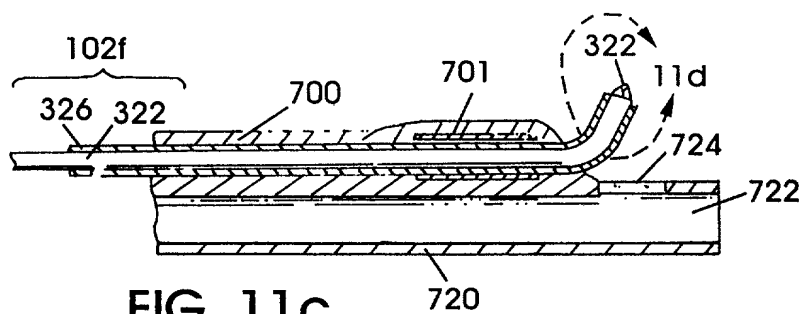


FIG. 11c

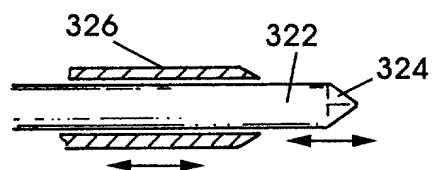


FIG. 11d

**FIG.12 a**

FIG.12 a is a cross-sectional view of a semiconductor device. It shows a substrate 50 with a layer 102. A gate structure 100p is on the left, connected to a gate 102. A vertical structure 102 is on the right, connected to a layer 724. A layer 720 is at the bottom. A layer BV1 is on the right, and a layer BV2 is on the top. A dashed line IF is shown at the top.

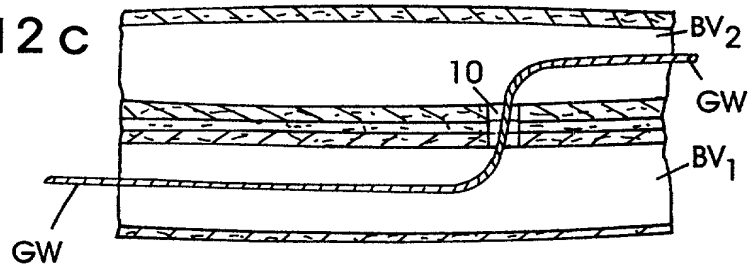
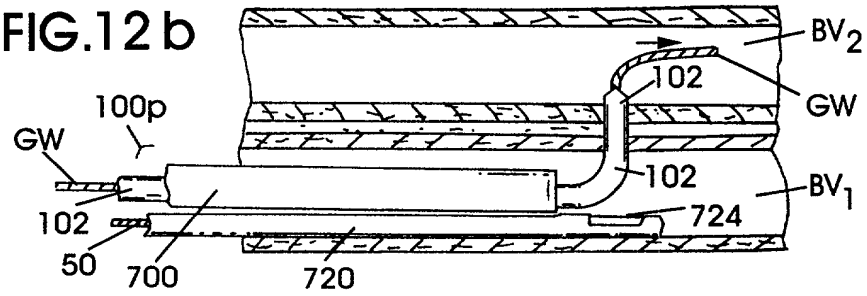
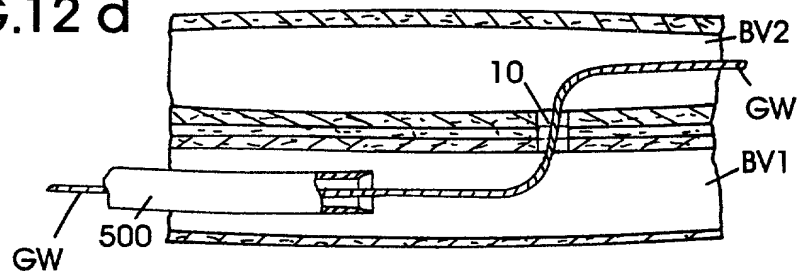
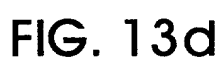


Fig. 12d is a cross-sectional view of a device. It shows a substrate with three distinct layers: a top layer labeled BV2, a middle layer labeled GW, and a bottom layer labeled BV1. A component labeled 10 is embedded within the GW layer. A component labeled 500 is positioned below the substrate, connected to the component 10 by a wire labeled GW. The wire GW enters the substrate from the bottom, passes through the BV1 layer, and connects to component 10.





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Dawn L. Mangino  
(Typed or printed name of person mailing paper or fee)  
Dawn L. Mangino 2/28/97  
(Signature) Date

Attorney's Docket No. TRNSV-001A

## COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR C-I-P)

As a below named inventor, I hereby declare that:

### TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

- ☒ original.  
☐ design.  
☐ supplemental.

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

- ☐ national stage of PCT.

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

- ☐ divisional.  
☐ continuation.  
☐ continuation-in-part (C-I-P).

### INVENTORSHIP IDENTIFICATION

**WARNING:** If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### TITLE OF INVENTION

METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS

AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES

008077 6680260

# SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b) or (c))

(a) ☐ is attached hereto.

NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed;  
or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) ☒ was filed on October 11, 1996, as ☒ Serial No. 08 / 730,327  
or ☐ \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and application number (consisting of the series code and the serial number; e.g., 08/123,456);

"(2) name of inventor(s), serial number and filing date;

"(3) name of inventor(s) and attorney docket number which was on the specification as filed;

"(4) name of inventor(s), title which was on the specification as filed and filing date;

"(5) name of inventor(s), title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

"(6) name of inventor(s), title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number; e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."

Notice of July 13, 1995 (1177 O.G. 60).

(c) ☒ was described and claimed in PCT International Application No. PCT/US96/16483, filed on 10/11/96 and as amended under PCT Article 19 on \_\_\_\_\_ (if any).

(Declaration and Power of Attorney [1-1]—page 2 of 7)

**ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

*(also check the following items, if desired)*

- ☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
- ☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

**PRIORITY CLAIM (35 U.S.C. § 119(a)-(d))**

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

*(complete (d) or (e))*

- (d) ☐ no such applications have been filed.
- (e) ☒ such applications have been filed as follows.

**NOTE:** Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

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I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

FILING DATE

10/13/95  
02/02/96

☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

(RcL67-396 Pub.675)

**ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

**POWER OF ATTORNEY**

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

*(list name and registration number)*

Kit M. Stetina, Reg. No. 29,445; Bruce B. Brunda, Reg. No. 28,497;  
Robert D. Buyan, Reg. No. 32,460; Mark B. Garred, Reg. No. 34,823;  
William J. Brucker, Reg. No. 35,462; Norman E. Carte, Reg. No. 30,455;  
Matthew A. Newboles, Reg. No. 36,224; Thomas C. Naber, Reg. No. 26,777

*(check the following item, if applicable)*

- ☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

**SEND CORRESPONDENCE TO**

Atty: Robert D. Buyan, Esq.  
STETINA BRUNDA & BUYAN  
24221 Calle de la Louisa, Ste. 401  
Laguna Hills, CA 92653

**DIRECT TELEPHONE CALLS TO:**  
*(Name and telephone number)*

Atty: Robert D. Buyan  
(714) 855-1246

**DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(Declaration and Power of Attorney [1-1]—page 5 of 7)

00970693-10800



SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

Joshua (GIVEN NAME) (NMI) Makower (FAMILY (OR LAST NAME))

Inventor's signature X

Date X 2/7/97 Country of Citizenship U.S.A.

Residence 177 Yerba Buena Ave., Los Altos, CA 94022

Post Office Address 177 Yerba Buena Ave., Los Altos, CA 94022

Full name of second joint inventor, if any

J. (GIVEN NAME) Christopher (MIDDLE INITIAL OR NAME) Flaherty (FAMILY (OR LAST NAME))

Inventor's signature X

Date X 2/7/97 Country of Citizenship U.S.A.

Residence 766 La Prenda Road, Los Altos, CA 94024

Post Office Address 766 La Prends Road, Los Altos, CA 94024

Full name of third joint inventor, if any

Timothy (GIVEN NAME) R. (MIDDLE INITIAL OR NAME) Machold (FAMILY (OR LAST NAME))

Inventor's signature X

Date X 2/7/97 Country of Citizenship U.S.A.

Residence 65 Bernal Avenue, Moss Beach, CA 94038

Post Office Address 65 Bernal Avenue, Moss Beach, CA 94038

(Declaration and Power of Attorney [1-1]—page 6 of 7)

(check proper box(es) for any of the following added page(s)  
that form a part of this declaration)

- ☒ Signature for fourth and subsequent joint inventors. Number of pages added  
3.

\* \* \*

- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. Number of pages added \_\_\_\_\_.

\* \* \*

- ☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. Number of pages added \_\_\_\_\_

\* \* \*

- ☐ Added page for signature by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)

\* \* \*

- ☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

☐ Number of pages added \_\_\_\_\_

\* \* \*

- ☐ Authorization of attorney(s) to accept and follow instructions from representative.

\* \* \*

(if no further pages form a part of this Declaration,  
then end this Declaration with this page and check the following item)

- ☐ This declaration ends with this page.

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Attorney's Docket No. TRNSV-001AADDED PAGE TO COMBINED DECLARATION AND POWER OF  
ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Full name of fourth joint inventor, if any

JasonBrianWhitt

GIVEN NAME

MIDDLE INITIAL OR NAME

FAMILY (OR LAST NAME)

Inventor's signature X JasonDate X 2/7/97 Country of Citizenship U.S.A.Residence 2616 Leavenworth Street, San Francisco, CA 94133Post Office Address 2616 Leavenworth Street, San Francisco, CA 94133

Full name of fifth joint inventor, if any

PhilipChristopherEvard

GIVEN NAME

MIDDLE INITIAL OR NAME

FAMILY (OR LAST NAME)

Inventor's signature X Philip C EvardDate X 2-7-97 Country of Citizenship U.S.A.Residence 3192 Bryant Street, Palo Alto, CA 94306Post Office Address 3192 Bryant Street, Palo Alto, CA 94306

Full name of sixth joint inventor, if any

PatrickEdwardMacaulay

GIVEN NAME

MIDDLE INITIAL OR NAME

FAMILY (OR LAST NAME)

Inventor's signature X Patrick E MacaulayDate X 2/7/97 Country of Citizenship U.S.A.Residence 3268 Flintview Court, San Jose, CA 95148Post Office Address 3267 Flintview Court, San Jose, CA 95148

Attorney's Docket No. TRNSV-001A

ADDED PAGE TO COMBINED DECLARATION AND POWER OF  
ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORS

Full name of <sup>seventh</sup> ~~fourth~~ joint inventor, if any THOMAS 3827/97  
John Timothy Garibotto  
 GIVEN NAME MIDDLE INITIAL OR NAME FAMILY (OR LAST NAME)  
 Inventor's signature X [Signature]  
 Date X 2/7/97 Country of Citizenship U.S.A.  
 Residence 6284 Lido Court, Newark, CA 94560  
 Post Office Address 6284 Lido Court, Newark, CA 94560

Full name of <sup>eighth</sup> ~~fourth~~ joint inventor, if any  
Claude A. Vidal  
 GIVEN NAME MIDDLE INITIAL OR NAME FAMILY (OR LAST NAME)  
 Inventor's signature X [Signature]  
 Date X 2-27-97 Country of Citizenship U.S.A.  
 Residence 5426 San Patricio Dr., Santa Barbara, CA 93111  
 Post Office Address 5426 San Patricio Dr., Santa Barbara, CA 93111

Full name of <sup>ninth</sup> ~~sixth~~ joint inventor, if any  
Russell J. Redmond  
 GIVEN NAME MIDDLE INITIAL OR NAME FAMILY (OR LAST NAME)  
 Inventor's signature X [Signature]  
 Date X 2/27/97 Country of Citizenship U.S.A.  
 Residence 1148 North Fairview Ave., Goleta, CA 92117  
 Post Office Address 1148 North Fairview Ave., Goleta, CA 92117

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Attorney's Docket No. TRNSV-001AADDED PAGE TO COMBINED DECLARATION AND POWER OF  
ATTORNEY FOR SIGNATURE BY FOURTH AND SUBSEQUENT INVENTORSFull name of <sup>tenth</sup> joint inventor, if anyThomas(NMI)Banks

GIVEN NAME

MIDDLE INITIAL OR NAME

FAMILY (OR LAST NAME)

Inventor's signature

\* Thomas BanksDate 2-27-97 Country of Citizenship U.S.A.Residence 4002 Via Lucro, Santa Barbara, CA 93110Post Office Address 4002 Via Lucro, Santa Barbara, CA 93110Full name of ~~fifth~~ joint inventor, if any

GIVEN NAME

MIDDLE INITIAL OR NAME

FAMILY (OR LAST NAME)

Inventor's signature

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_

Full name of ~~sixth~~ joint inventor, if any

GIVEN NAME

MIDDLE INITIAL OR NAME

FAMILY (OR LAST NAME)

Inventor's signature

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence \_\_\_\_\_

Post Office Address \_\_\_\_\_